HEALTH & DISEASE — PHARMACISTS

1994 - 1996

Pharmacy Council ire

(96)

B/Day 4/3/94

PRETORIA — The "wilful" withholding of certain medicines was creating uncertainty among the public and prescribers, the SA Pharmacy Council said yesterday.

The medicines were being withheld from pharmacies by some wholesalers because manufacturing companies had decided also to distribute medicines through a newly formed wholesale distribution company, in competition with existing wholesalers.

Although the council usually refrained from becoming involved in a purely commercial issue between persons registered with it, it was committed to maintaining ethical norms.

The council required that pharmacists place patients' interests first and regarded in a serious light any act or omission by a pharmacist which could be to patients' detriment. — Sapa.

Political comment in this issue by J Jones; newsbills by D Armour; headlines and subediting by C Pickard-Cambridge; all of 11 Diagonal Street, Johannesburg.

Pharmacies prepare for price war

(91)

BY CLAIRE BISSEKER
STAFF REPORTER

PHARMACISTS are prepared for a medicine price war to put dispensing doctors out of business.

The Pharmaceutical Society of SA (PSSA) is investigating a new pricing scheme which will eliminate the profit incentive in the sale of medicines at retail level, the Cape Times heard this week.

Instead of a current 50% retail mark-up on medicine, it is envisaged that pharmacists will charge their cost price plus a professional handling fee, expected to be below R10 per prescription.

The result will be a substantial reduction in the price of medicine and will effectively put dispensing doctors out of business, said PSSA executive director Mr Ivan Kotze.

"Unless dispensing doctors sell at cost, they will be by-passed by medical aid schemes who will only allow members to buy medicines where they are cheapest — from pharmacies."

Without a profit-linked mark-up, pharmacists will have no incentive to sell relatively more expensive medicines in larger volumes than necessary.

In response, a spokesman for Dr Christo Botha, chairman of the National General Practitioners Group, released a statement saying doctors' prices were often much cheaper than some retail outlets because they were prepared to dispense medicine in the most cost-effective way possible by passing any savings on to their patients.

But pharmacists claim that dispensing doctors were able to undercut the pharmaceutical industry only because of substantial discounts from wholesalers.

A city pharmacist told the Cape Times yesterday he was quoted half the wholesale price for a pack of contraceptive pills last week when he phoned a wholesaler pretending to be a dispensing doctor.

Mr Kotze said this arrangement had given rise to the "widespread" illegal practice of some doctors selling medicines to pharmacists by offering prices below what pharmacists could get from wholesalers.

The PSSA hopes their scheme will enjoy the co-operation of all pharmacists, but are prepared to enforce it through legislation if it is approved by the PSSA executive committee in April.

Mr Kotze claimed pharmacies were being "wrung dry" as they were forced to grant medical aid schemes discounts of up to 30% per prescription, or face losing all the scheme's members. Some medical aid schemes did not pass these discounts on to members.

As the new pricing system would eliminate retail price mark-ups, he was expecting resistance from medical aid schemes who relied on the 50% mark-ups to claim their hefty discounts, Mr Kotze said.

Representative Association of Medical Schemes (Rams) executive director Mr Reg Magennis said the medical schemes industry would resist any move which reduced their savings, but added that objections would be short-lived if their overall costs decreased through cheaper medicines. He said medical schemes would welcome any move which reduced the incentive among dispensing doctors and pharmacists to over-prescribe and charge too much.

CT 7/3/95

Decline reverses at pharmacy schools

BIDAY 10/3/94

BEATRIX PAYNE

STUDENTS registering to study pharmacy at SA's training institutions increased this year after declining since 1986, says Medunsa pharmaceutical school senior lecturer Dr Beverly Summers.

Summers said research completed during 1993 showed that "as a source of new pharmacists", Potchefstroom declined more than 30% from 157 in 1987 to 108 in 1991, while pharmacy graduates from Rhodes fell more than 50% from 89 in 1985 to 43 in 1991.

Research had also shown a 34,4% drop in the number of pharmacists registered from 1986 to 1992, while the number of pharmacists leaving the profession over the past few years had increased.

As a profession, pharmacy had lost much of its attraction. "Private sector community pharmacies have been threatened by an increase in the number of dispensing doctors," Summers said.

The rationalisation of institutions teaching pharmacy, introduced almost four years ago, had exacerbated the problem. Technikons in Natal, Pretoria and Johannesburg have had to close their faculties, leaving the University of the Western Cape, Rhodes, Potchefstroom and the University of Port Elizabeth to train most students.

Medunsa continued to train only postgraduate students in spite of repeated calls for it to expand its teaching facilities, Summers said.

Manpower problems had sparked concern among pharmacists and training institutions.

They had tried to redress the shortfall in the number of students by shifting the focus of course content and embarking on more aggressive advertising campaigns.

Rhodes pharmacy faculty dean Dr Beverly Williams said the faculty was operating at almost full capacity this year. More than 500 new students had applied for admission in 1994, but only 120 places were available.

Certain aspects of the first-year curriculum had been changed to cater for students not familiar with some subjects. A mentoring system had also been introduced to assist second-year students.

Student numbers had increased this year, but an increase in the number of registered pharmacists would only be seen at the end of 1997 when this year's class graduated, she said.

Potchefstroom University dean of pharmacy Prof Boeta Koeleman said there had been a "tremendous" increase in numbers in the faculty this year. Changes in legislation enabling pharmacists to increase their clinical role had given students greater confidence in the future of the profession.

Old people 'often given overdoses'

(96)

Staff Reporter CT 17/5/94

A SOUTH AFRICAN study of 90 elderly patients has revealed that 77% were receiving one or more drugs at above the recommended geriatric dose.

This emerged yesterday at a the National Pharmaceutical Society conference in Sun City.

The study also established that potential drug interactions were identified in 64% of patients and duplicative therapy in 34%.

Professor Ian Wiseman, head of pharmacy at the University of Port Elizabeth, said at the conference that many pharmacists had to play a "policing" role with doctors.

"Often the only contact the pharmacist has with a doctor is to inform him of a mistake that has been made, or of a piece of information omitted from the prescription," Prof Wiseman said.

Guidelines

Dr Bernard Mandell, chairman of the Medical Association of South Africa's Federal Council, said yesterday he welcomed the plea for greater co-operation between the medical profession and pharmacists.

"We are therefore concerned about the implication that doctors' prescriptions are invariably incorrect and should be checked by pharmacists," Dr Mandell said.

He said MASA would study the report with a view to further consultation.

"Should it be indicated, guidelines for appropriate geriatric care will also be developed in consultation with expert practitioners," he said.

Better health for all the aim

Sowetan 19/5/94

THE Pharmaceutical Society of South Africa is pressing for changes to the Medicines Control Act in the interests of better health for all in South Africa, the society's president, Mr Gary Kohn, said on Tuesday.

He delivered a report at the PSSA's annual national conference at Sun City. (96)

Kohn said while access to higher schedules was still pending, the PSSA was encouraging its members to equip themselves to obtain Section 21 permits allowing access to certain Schedule 3 and Schedule 4 medicines for specified ailments.

Kohn reported the society had been instrumental in training pharmacists to obtain family planning permits, 2 200 of which had been issued so far. A further 380 pharmacists were awaiting permits after passing their November 1993 examinations.

Turning to the extended role proposed for pharmacists, Kohn said there appeared to be areas of contradiction between the Pharmacy Act 101 of 1965, and the Medical and Dental Act 56 of 1974.

He drew pharmacists' attention to section 36 (3) of the Medical and Dental Act which, he said, determined that a registered pharmacist might perform certain duties, even though they were defined by the Medical and Dental Act as ones that could be performed only by a doctor.

He said this led to the question whether it was the Act's intention for pharmacists to diagnose a condition and prescribe medicine, or were they allowed only to dispense medicines upon request or on prescription?

Dispensing doctors remained a major issue and high level discussions were being held to break the impasse.

Kohn reminded delegates that pharmacists could supply medicines upon the written or oral prescription of a nurse. It had been established that the nurse would, under certain conditions, become a prescriber and provider of medicines. The list of medicines would be limited. — *Sapa.*

PHARMACIES

No antidote for reform

Pharmacists, it seems, remain more determined than ever to hold on to their near-monopoly of drug sales to the public.

Pharmaceutical Society of SA president Gary Kohn this week again stressed that the present network of pharmacies needs to be maintained at all costs. "The pharmacy as a small business enterprise must be recognised as important and in the public interest," he told delegates to the society's 49th annual conference at Sun City. FM

Also tabled at the conference was a motion calling on the Pharmacy Council — statutorily constituted to protect the public interest but made up of a large number of pharmacists — to maintain pharmacy ownership firmly in the hands of registered pharmacists. 20/5/94

The motion, however, was withdrawn after the council's Johan van der Walt emphasised its commitment to keeping ownership with the pharmacist. Confirming that the council last year managed to scuttle the deregulation of pharmacy ownership by opposing the final draft of the Pharmacy Amendment Bill — which would have given the Health Minister the right to approve applications from Clicks, Pick 'n Pay and other non-pharmacists to open pharmacies — Van der Walt nevertheless stresses the importance of allowing controlled deregulation at the retail level. (96)

"Government advisers and business are still applying pressure to deregulate the sector."

Van der Walt envisages a situation where limited non-pharmacist ownership of pharmacies is allowed, at the sole discretion of the council — a suggestion the Competition Board last year threw out as not being in the public's best interest.

The board was concerned that the council would largely prevent deregulation of the sector by setting difficult criteria for non-pharmacist applications.

Van der Walt suggests that the council will consider an application from a non-pharmacist to open a pharmacy in an area where there is none. Of course, this type of thinking could exclude the large retail chains that tend to operate in busy places where often there are lots of little pharmacies operating mostly on inefficient economies of

FM 20/5/94

scale.

Pharmacists are also concerned about the proliferation of mail-order drug suppliers. In recent months these operations have managed to undercut the 50% mark-up pharmacists add to the wholesale price (which is 17% more than the manufacturer's price) by operating largely from cheaper warehouse-type premises and employing fewer staff. Kohn alleges that the pharmacist, in such an undertaking, is unable properly to fulfil his core function of promoting the safe and effective use of medicines. 96

Of course critics would argue that drugs-by-post has proved successful and cost-effective in the US and is supplemented by a toll-free phone advice bureau.

Pharmacists, however, are considering replacing their traditional 50% markup (less discounts) with a professional fee that would cover dispensing, advice and follow-up monitoring. ■

Pharmacists seek wider power to dispense drugs

B/Day 23/5/94

BEATRIX PAYNE

THE Medicines Control Council (MCC) would ask Health Minister Dr Nkosazana Zuma to allow pharmacists to dispense without prescription drugs such as the Pill and treatments for cholera, MCC director Johan Schlebusch said at the weekend.

But pharmacists would only be able to dispense such "high schedule" medicines once they had received the appropriate training in diagnosis and treatment.

Industry sources said the move could lower health care costs and widen public access to such drugs.

Pharmaceutical Society of SA president Cecil Abramson welcomed the move as "long overdue" and one which would allow pharmacists to bring "real medicine to the people".

"This is a good starting point. Once we can show we can handle the dispensing of these drugs maybe we will have access to additional medicines," he said.

Health care costs could be cut if pharmacists were allowed to dispense higher schedule drugs as patients would no longer need to pay consultation fees for a doctor's script, Abramson said.

But he emphasised that doctors' services would not be bypassed as pharmacists would refer patients to doctors if necessary.

Abramson said most pharmacists were prepared to undergo additional training to allow them to dispense higher schedule medicines.

(96)

"Much of the training needed is already being practised in the pharmacy but needs to be taught in theory."

The latest PSSA journal said drugs under consideration included insulin, asthma treatments and oral and injectable contraceptives under schedule three; certain schedule four drugs for the treatment of bronchitis, sexually transmitted diseases and bacillary dysentry; and a schedule five injection for epilepsy.

Outgoing PSSA president Gary Kohn said access by pharmacists to higher schedules should not be a replacement for care by the medical practitioner.

He said the Pharmacy Council would closely monitor the actions of pharmacists who had acess to higher schedule drugs.

A retail pharmacist welcomed the possibility of increased access to certain drugs but said training was crucial. "We must have some form of control or some pharmacists could prescribe incorrect medicines."

He said drugs were scheduled to protect the patient from misprescriptions.

Sleeping pills which could be fatal in large quantities were registered under schedule five to control public access to them.

'Need for affirmative action in pharmacy

B/Day 25/4/94

BEATRIX PAYNE

AFFIRMATIVE action was necessary in the pharmacy industry as the lack of pharmacies in SA's rural areas and townships stemmed from a lack of black pharmacists, Medunsa pharmaceutical lecturer Dr Beverly Summers said yesterday.

Research completed by Summers in 1993 and recently published in the SA Pharmaceutical Journal showed that 90% of all pharmacists in SA were white.

She said the small number of black pharmacists was related to the lack of role models for students and the fact that few matriculants considered pharmacy as a career.

The problem was not in the industry itself as there was great demand for "a qualified personable black pharmacist".

The industry should start a public relations campaign aimed at encouraging matriculants to become pharmacists. Better training was needed at high school level as maths and science qualifications "were poor".

She also suggested that pharmacy graduates should complete a period of "national service" by working in rural areas when they were qualified.

Research had shown that the biggest proportion of pharmacists were based in the PWV and served only 25% of SA's population.

This "gross maldistribution" of pharmacists by race and geographical region had exacerbated distortions in the provision of health care. "There are very few community pharmacies in black areas because there are few black pharmacists," she said.

Rather than using financial incentives to encourage pharmacists to work in rural areas, it would be better to train people who lived in those areas.

Pick 'n Pay criticises pharmacies' society

BDay 26/5/94

BEATRIX PAYNE

RETAIL chain Pick 'n Pay has criticised the Pharmaceutical Society of SA (PSSA) for its stand against deregulation.

Pick 'n Pay deputy MD Sean Summers said that deregulation would cut health care costs, and that legislation controlling pharmacy ownership was "archaic and anachronistic". (96)

"We are still waiting for the much discussed changes to legislation to take place," he said. "The most important issue is costs in health care, and these will be reduced if the ownership of pharmacies is deregulated."

Summers said pharmacists were hiding behind the legislation and seeking their own preservation.

PSSA president Cecil Abramson said the society opposed deregulation because ethical practices could be compromised by the profit demands of large retail chains.

Ownership of pharmacies sparked caustic debate in the industry last year when former Health Minister Rina Venter attempted to pass legislation deregulating pharmacy ownership.

If passed the legislation would have allowed retail chains to own and operate pharmacies on their premises.

Sources in the industry said they were waiting for clear guidance from the new government. But the ANC's health secretary Dr Ralph Mgijima said it had not yet taken a definite stand and would explore the issue further.

The ANC had fought hard to have the Bill withdrawn last year as its consequences had not been properly considered.

Mgijima was concerned that supermarkets with pharmacies could decimate business for small pharmacies. Retail chains might not stick to the ethical norms that govern the dispensing of medicines by pharmacists, he said.

"We don't believe in satisfying the interests of one stakeholder at the expense of others," he said.

☐ SA Druggists' pharmacy franchise chain Link has introduced a charge card that could introduce a "totally new market" into pharmacies and improve business for dispensaries in the chain, the company announced yesterday.

of violence and reconciliation, speaks
rime awareness week, which is to be
13. Picture: ROBERT BOTHA

cripple magazines'

R233m total.

an on tobacco advertising would not
e serious adverse economic effects,
would rather promote health", the
said.

C researcher Dr Derek Yach said
e-mongering" by the tobacco indus-
as intended "to put advertising jobs
ublic health at loggerheads". — Sapa.

Groundwater control strategy in pipeline

B/Day 21/8/94

MICHAEL MOON

A STRATEGY to manage the quality of groundwater is being developed by the Water Affairs Department.

Utilisation of groundwater would play a major role in satisfying the demands of government's reconstruction and development programme, the department said this week.

"Increasing levels of development, urbanisation and industrialisation pose a threat to groundwater through over-abstraction and contamination," it said.

Numerous cases of severe groundwater contamination had been discovered and reported recently.

Groundwater represented the sole source of supply for many small urban and rural communities, and was becoming increasingly important in terms of community water supply, the department said.

Mining operations were the main source of contamination of groundwater, a spokesman for the consulting firm co-ordinating the project said yesterday.

The pollution came from both underground workings and seepage from surface materials, he said.

Coal mines posed the biggest problem, due to the sulphide minerals in coal and the fact that operations were conducted relatively close to the surface, assistant project co-ordinator Greg Wells said.

Sewage pollution from informal settlements, particularly in dolomitic areas, was also a hazard, he said.

Over-abstraction, or excessive pumping, sometimes allowed inferior quality water from other areas to seep through into productive wells.

In coastal areas, salt water often spoiled over-used sources.

"Since groundwater represents a source of water supply to many people, the sources of pollution must be managed carefully to ensure that the groundwater supply is sustainable in the long term. This will involve the use of a wide range of both statutory and non-statutory regulatory measures,"the department said.

A comprehensive management strategy was necessary to co-ordinate the implementation of such regulations.

"Future generations must have access to adequate supplies of acceptable water."

Government has called for all interested and affected parties to participate in developing the new strategy.

Wells said it was believed that there were at least 1 200 such parties throughout the country.

At present the level of interest and availability of these organisations and individuals to participate was being gauged.

Various types of input from numerous sources would be dealt with by the co-ordinators, Wells said.

Focus on medicines pricing

B/Day 21/8/94

BEATRIX PAYNE

PHARMACEUTICAL wholesalers, manufacturers and medical aids would meet later this month to discuss restructuring the medicines pricing system, National Association of Pharmaceutical Wholesalers executive director Trevor Phillips announced yesterday.

"The association feels that the health care industry cannot afford to work much longer under the current opaque system," he said.

The introduction of a "cost-plus" pricing system would mean transparency and the end of mark-ups and discounts based on the "blue book", Phillips said.

But Pharmaceutical Society of SA president Cecil Abramson said he was waiting for the report of the cost-plus working group — due some time this week — before the society would convene another meeting of the cost-plus committee.

He said the report had been drawn up by representatives from the association, pharmaceutical multinationals and medical aids, and was intended as a discussion document.

Abramson added that the report was likely to recommend the use of a mark-up system.

The society supported the mark-up system and believed "the existing system of add-on and discounts has to stop," he said.

A change in the pricing structure would have a knock-on effect from manufacturer to end user and as a result several interest groups were involved in planning the changeover.

But not all members of the committee were happy about a cost-plus system. Some private hospital groups had expressed reservations.

Pharmacists working in private hospitals were paid a lower professional fee than their colleagues in private practice, Abramson noted, and their income would be further reduced if the base cost of medicines were to fall.

Cost-plus working group chairman David Boyce could not be reached for comment.

Union warning on farm interest rates

B/Day 21/8/94

LOUISE COOK

THE union representing SA's black farmers has warned that proposals for government's White Paper on agriculture concerning market-related interest rates for land purchases could thwart attempts to widen black land ownership.

The National African Farmers' Union, which sits on the Wit Committee appointed to draw up the new agriculture policy, said yesterday that moving to market-related interest rates was "totally unacceptable".

Union spokesman Thabo Mokane said border farmers had bought farms at a 4% interest rate. Yet the committee was proposing market-related rates just as SA was attempting to expand black empowerment.

Meanwhile Wit Committee chairman Chris Blignaut said marketing proposals in a report compiled under the previous government heralded some of the changes likely to be contained in the White Paper. These strongly favoured deregulation.

Health focus

Pledge will help UWC meet demands for pharmacists

Southeaster (Suppl. to South)

SOUTH Africa will need another 7 000 pharmacists by the year 2000, according to Professor Peter Eagles, head of the school of pharmacy at the University of Western Cape (UWC).

He was speaking at the presentation of a pledge by pharmaceutical manufacturers Warner-Lambert to provide substantial support to the school's expansion.

There are 9 000 registered pharmacists in South Africa. Research indicates that by 2000 South Africa will need at least 16 000 pharmacists to cope with population growth and the extension of appropriate services to all communities, Professor Eagles said.

"The re-evaluation of health provision in South Africa is an integral part of the Reconstruction and Development Programme and the university is playing its part by initiating a rigorous inquiry into the country's primary health care needs.

"At UWC we are committed to producing pharmacists well schooled in the primary health care approach and adept at using this approach in combination with pharmaceutical technologies.

"All of these abilities must have as their focus the bringing of appropriate and adequate medicines and systems to all South African citizens," said Professor Eagles.

The presentation was made by Warner-Lambert chief executive, Mr Tim Largier, who emphasised the company's commitment to fostering ties between the private sector and educational institutions, in the interest of advancing research and development. He expressed his admiration for the idea of a larger school.

DONATION: At the presentation of Warner-Lambert's donation to UWC's school of pharmacy were, from left, UWC acting rector Jaap Durand, Warner-Lambert CEO Tim Largier, UWC director of Development and Public Affairs Stan Ridge and Peter Eagles of the UWC school of pharmacy

96

"We consider the UWC school of pharmacy to be an extremely valuable resource and see an important role being played by Warner-Lambert together with UWC in facing the challenges of the future," Mr Largier said.

UWC acting rector, Professor Jaap Durand, said Warner-Lambert's assistance to the pharmacy school had made a huge impact and that they were one of the institution's largest donors.

UWC is involved in a R11 million fund-raising drive for the expansion of the school.

According to Professor Peter Eagles, Warner-Lambert's support will be of assistance in the provision of subject-dedicated laboratories and other specialised facilities.

Pledge to curb soaring costs

Zuma warns of medicine price control

Star 18/8/94

■ BY CHRIS WHITFIELD
POLITICAL CORRESPONDENT

Cape Town — Health Minister Dr Nkosazana Zuma has warned of "drastic steps" to curb soaring costs of medicine — including possible price controls and changes to the "monopoly of pharmacies". (96)

The Minister signalled in a mini-debate in Parliament yesterday that she intended tackling the issue vigorously.

Zuma was responding to MPs' charges that some pharmacists were engaged in profiteering and that prices in South Africa were vastly more expensive than those around the world.

She revealed that her department had set up a committee which would thrash out a pharmaceutical policy.

One of its briefs would be to develop a "one price" medicine scheme for both the private and public sectors.

Other tasks of the committee would include compiling an essential-medicines list for the public sector and considering strategies to increase the use of generic medicines.

"We may have to look at reintroducing price control," the Minister said.

IFP MP Dr Dennis Madide said: "The problem is purely and simply profiteering."

Fellow IFP MP Farouk Cassim said medicines in South Africa were 120 percent more expensive than in the US and 600 percent more than in India.

Democratic Party MP Mike Ellis said wholesalers put a 21,3 percent mark-up on medicines and then retail pharmacies added a 50 percent mark-up.

Pharmacist may operate on chain store premises

B/Day 31/8/94

BEATRIX PAYNE

THE Pharmacy Council has taken the first step towards widening access to prescribed medicines, giving the go-ahead to a Pietersburg pharmacist to practice inside an OK Bazaars chain store.

However, Pharmacy Council acting registrar Noel Pretorius said yesterday the pharmacy could be owned only by a registered pharmacist.

The move was in line with Health Minister Nkosazana Zuma's recent announcement that she was considering allowing the sale of scheduled drugs in supermarkets and had appointed a drug policy commission to examine the issue.

Retail sources said chain stores should be allowed to own pharmacies if the cost of medicines was to be cut.

Pretorius said the Pietersburg pharmacy would also have to provide a 24-hour service directly or indirectly and would have to be in a secure enclosure to ensure that unauthorised persons did not gain access to scheduled drugs.

Pick'n Pay deputy MD Sean Summers said pharmacy ownership should be deregulated. "The current regulations are a sham. At the end of the day the Pharmacy Council controls what the pharmacists do."

He said the council had a vested interest and it would be difficult to bring down the cost of medicines without deregulating ownership.

Zuma's plan to allow supermarket pharmacies is part of an overall strategy to bring down health costs.

Drug policy committee member Marisa Jacobs said the committee was investigating whether deregulating ownership would lower medicine prices and increase public access to pharmaceutical care.

"We have not yet drawn up a policy," she said. "In terms of the free market, ownership should be deregulated, but it does not neccesarily follow that prices will drop."

Pharmaceutical Society of SA president Cecil Abramson said there was no proof that prices would fall if chain stores owned pharmacies. Professional standards would be compromised if the chain store owning the pharmacy dictated the terms of trade, he said.

OK Bazaars legal director Trevor Cohen said the company did not want to employ pharmacists. It would rather lease space to a pharmacist.

(96)

(96) ST 15/1/95

Board to investigate 'listed pharmacies'

By CAS St LEGER

THE Competition Board is to investigate complaints that some medical or benefit schemes issue lists of preferred pharmacies to be used for prescriptions.

A Sandton pharmacist told the Sunday Times he intended seeking legal advice on one such list.

The board will investigate allegations of restrictive practices which include alleged obligatory purchases from wholesalers and the alleged leverage that medical scheme contracts afford certain wholesalers. Written and oral representations — by telephone or in person — will be taken from next Friday.

This issue is separate from the board's recent investigation into discriminatory pricing. The prohibition on such pricing was taken on appeal by five multinational pharmaceutical companies.

Board official Woter Meyer said details of this investigation would be published in the Government Gazette on January 20.

9

Chemists 'going out of business'

96

ARGUS 25/1/95

The Argus Correspondent

JOHANNESBURG. — Pharmacists are up in arms over what they see as "unsavoury" medical aid practices that are "putting pharmacies out of business".

In a spot survey, pharmacists in Johannesburg said they were going to the wall.

Those still liquid claimed to be running at a net profit of between one and five percent.

A predominant feeling was that 20 percent of pharmacies would go out of business within the next year.

Executive director of the Association of Community Pharmacists David Pleaner said : "There are some very unsavoury things going on in this business that are effectively putting pharmacies out of business.

"The problem stems from the fact that medical schemes are doing everything in their power to maintain members, and to do this their members have to get medication from specific sources," he said.

Pharmacists said medical aid schemes were offering members 30 percent discounts if they used their drug sources.

While pharmacists are required by law to mark up the initial buying price by a maximum 33,4 percent, dispensing doctors and private hospitals have a mark up of 143 percent.

Pharmacists claimed this set up unfair competition between them.

Medical schemes said the recent spate of pharmaceutical bankruptcies was not linked to medical aid plans.

Stop mail-order medicine, say pharmacists

(96) ARG 9/2/95

LIBBY PEACOCK
Health Reporter

A CALL to shut down mail-order pharmacies has come from the local branch of the Pharmaceutical Society of South Africa which claims these "pharmacies" are a threat to community-based chemists, and are "splitting the patient profile in half".

The Cape Western Province branch will appeal to the SA Pharmacy Council to legislate against mail-order operations.

But Pharmacy Council registrar, Chris van Niekerk, said yesterday his council had formulated regulations and presented them to Health Minister Nkosazana Zuma, and was monitoring the activities of the mail-order pharmacies.

Gus Ferguson, director of the Cape Western Province branch of the Pharmaceutical Society, said his branch had met on Monday night to discuss the impact of mail-order medicine on community pharmacies.

He said some medical aid societies had arranged for patients to get their "chronic" medication from these pharmacies.

One of the motions accepted at the meeting was that the Pharmacy Council should be approached and asked to regulate, or legislate against, the mail-order pharmacies.

If the council wouldn't agree to do so, a vote of no-confidence would be recorded.

Mr Ferguson said while community pharmacies dealt with acute medication, mail-order pharmacies could send off medicine for chronic conditions.

It was estimated that up to 50 percent of medicine could be defined as "chronic".

This not only posed a financial threat to community-based pharmacies, but also reduced pharmacists' professional intervention and service.

The society always recommended that clients used a single pharmacy, where pharmacists could keep track of the medication they were on.

The mail-order pharmacies were "splitting patient profiles in half".

Mr Ferguson said while the Pharmacy Council was "not encouraging it", it had removed the ethical rule against it.

What annoyed the "profession at large" was that these pharmacies seemed to be mushrooming.

"If our estimate is correct that chronic medicine is 50 percent of all medicine, community-based pharmacies are threatened. If they disappear, it will be a loss to the community," he said.

Mr Van Niekerk responded that regulations had been formulated to control medicines sent by post.

These medicines had to be accompanied by specific information about the products.

The council preferred direct contact between patients and pharmacists, but also believed that patients had the right to choose from where they wanted to get their "chronic" medicine.

Mr Van Niekerk said the council had received a number of complaints from people who had received medicines which had been wrongly addressed, or broken, and was "monitoring" the situation.

WE'VE JUST WON

New pharmaceutical body

(96) KATHRYN STRACHAN

PHARMACEUTICAL manufacturers have formed an initiative to co-ordinate their contributions to developing a new health care system and to ensure a multidisciplinary approach in the process. BD 27/2/95

Adcock Ingram CEO Don Bodley said the group had been set up to co-operate with the Health Ministry in finding solutions to health problems, and to enable the pharmaceutical sector to play a more meaningful role.

The group, called the SA Health Care Initiative, was formed by Glaxo, Roche, Adcock Ingram, Logos, SA Druggists and pharmacy benefit management company TPS Mutual Trust.

Bodley said the initiative had set up task groups to address various issues. The first was looking at ways of using private sector resources to extend health services. The initiative believed this should be done by extending medical aid coverage. By making this coverage compulsory to all who were employed or self-employed, it would relieve much of the burden on the state.

Recommendations would be made to government on how to prevent the widespread theft of medicines through government depots — based on the extensive experience of the pharmacy sector.

DP lauds new price moves by chemists

BY BARRY STREEK
POLITICAL STAFF

CT 8/3/95

THE move by pharmacists to introduce a new pricing system to cut the cost of medicine was to be welcomed, the Democratic Party said yesterday.

The announcement in this regard by the Pharmaceutical Society and similar initiatives by wholesalers were important steps, the DP said in a statement issued by its health spokesperson, Mr Mike Ellis.

"Medicine costs have spiralled in recent years and the DP has always called for an investigation of the whole distribution chain of medicine from the manufacturer to the patient.

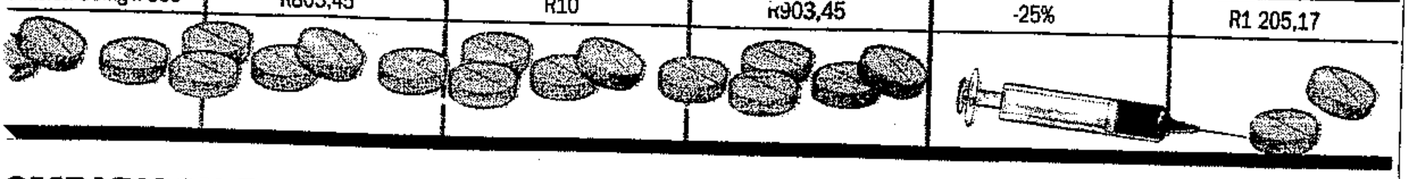
"These announcements now indicate a pro-active role on the part of two important components of the distribution chain and is most encouraging," Mr Ellis said in the statement.

He said the role of dispensing doctors needed urgent attention.

IOW THE NEW PRICING SYSTEM COULD REDUCE MEDICINE PRICES N PHARMACIES:

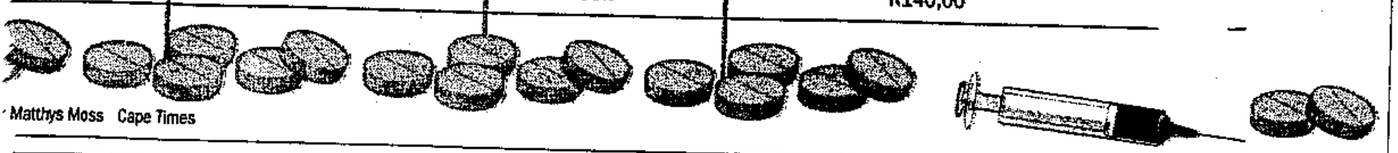
THE ENVISAGED SYSTEM

PRODUCT	PHARMACY'S COST PRICE +	R10 PROFESSIONAL FEE	= NEW PRICE	% REDUCTION	CURRENT AVERAGE SA RETAIL PRICE
dalat 10mg x 100	R147,95	R10	R157,95	-36%	R246,58
antac 150mg x 60	R283,27	R10	R293,27	-31%	R424,90
ecloforte 80 dose	R97,86	R10	R107,86	-26,5%	R146,78
entolin 2mg x [illegible]	R34,67	R10	R44,[illegible]	[illegible]%	R52,01
amicron 80mg x 500	R803,45	R10	R903,45	-25%	R1 205,17



OMPARISON BETWEEN STATE - TENDER V WHOLESALE PRICES

RODUCT	MANUFACTURE'S SELLING PRICE TO STATE	% INCREASE	MANUFACTURER'S SELLING
tac 150mg x 60	R53,58	336 %	R233,70
oforte 80 dose	R30,55	164%	R80,73
tolin 2mg x 100	R6,42	345%	R28,60
ac 20mg x 28	R84,36	66%	R140,00



Matthys Moss Cape Times

Medicine plan slated

CT 8/3/95 (96)

BY CLAIRE BISSEKER

A NEW medicine pricing scheme being investigated by the Pharmaceutical Society of South Africa (PSSA), which would reduce retail medicine prices to cost, came under fire yesterday from city pharmacists who claimed it would bankrupt the industry.

Instead of the current 50% retail mark-up on medicine, it is envisaged that pharmacists will charge their cost price plus a professional handling fee, expected to be below R10 per prescription.

The result will be a substantial reduction in the price of medicine and will effectively stop doctors dispensing medicines, says PSSA executive director Mr Ivan Kotze.

However, pharmacists told the Cape Times yesterday that unless they sold 50 prescriptions a day the scheme would force pharmacies to close down.

A city pharmacist, who preferred not to be named, said it would be impossible to pay his rent and staff on a R10 mark-up.

A Milnerton pharmacist said smaller pharmacies would not be economically viable under the new scheme.

In general, pharmacies would be annihilated unless they recovered the business taken from them by dispensing doctors, which was estimated at more than 50% of the trade, he said.

He said pharmacists were "being squeezed from both sides".

On the one hand was the dispensing doctor who obtained medicines at far lower wholesale prices, and on the other were the supermarkets which sold similar ranges of household items.

'Unaffordable'

A city pharmacist said the envisaged system was "ridiculous" as it would inflate the cost of cheap items but make more expensive items "unaffordable".

For example 12 Disprin, which have a retail cost price of R1,70, would sell for R11,70 under the new system, giving the pharmacist a profit of 588%.

But relatively expensive medicines like Diamicron diabetic tablets which have a cost price of R803,45, would sell for R903,45 instead of R1205 — a profit to the pharmacist of only 1,2%.

The PSSA said one of the advantages of the scheme was that it removed profit-linked mark-up and so pharmacists would have no incentive to sell relatively more expensive medicines in larger volumes than necessary.

The high cost of medicines in South Africa is also attributed to the cross-subsidisation of the state medical bill by the private sector.

South Africa has a two-tier pricing structure where the state, which purchases about 80% of all medicines sold in the country, demands at least a 20% discount on the net wholesale price.

In reality, the state can achieve discounts of more than 300%.

Pharmaceutical Manufacturing Association of SA executive director Mr John Toerien said the discrepancy between state and retail prices revealed that the private sector was subsidising the state.

However, he said mark-ups of over 300% "may be exceptions".

He said manufacturers could offer the state markedly lower prices because the state bought huge volumes which required less costly bulk packaging and paid cash after 30 days.

HEALTH — 1

Staking a claim to drug sales

(96) FM 24/3/95

In what is seen as an attempt to retain pharmacists' stranglehold on drug sales, SA's powerful Pharmacy Council has introduced a discussion document which proposes that retail pharmacists charge a professional fee and radically change the pharmaceutical pricing system.

In a nutshell, the proposal would replace the traditional 50% mark-up on drugs which retail pharmacists can charge with a professional fee that could be based on a R150 hourly rate. Added to this, the pharmacist would charge a fixed distribution fee which would probably not exceed 16% of a manufacturer's unit selling price.

But council resistrar Chris van Niekerk says the discussion document has led to the appointment of a task group to establish pricing mechanisims and to address the ownership of pharmacies issue. He says the document advocates a system which will allow and not inhibit price competition and create greater transparency in the medicines supply market. He adds the proposed system must be acceptable to medical schemes and allow pharmacists to receive adequate remuneration for services rendered.

Says Wits economics professor Duncan Reekie: "The proposal appears to be yet another attempt at collusive behaviour sanctioned by a professional cartel, allegedly working in the public interest but effectively bolstering an obsolete profession."

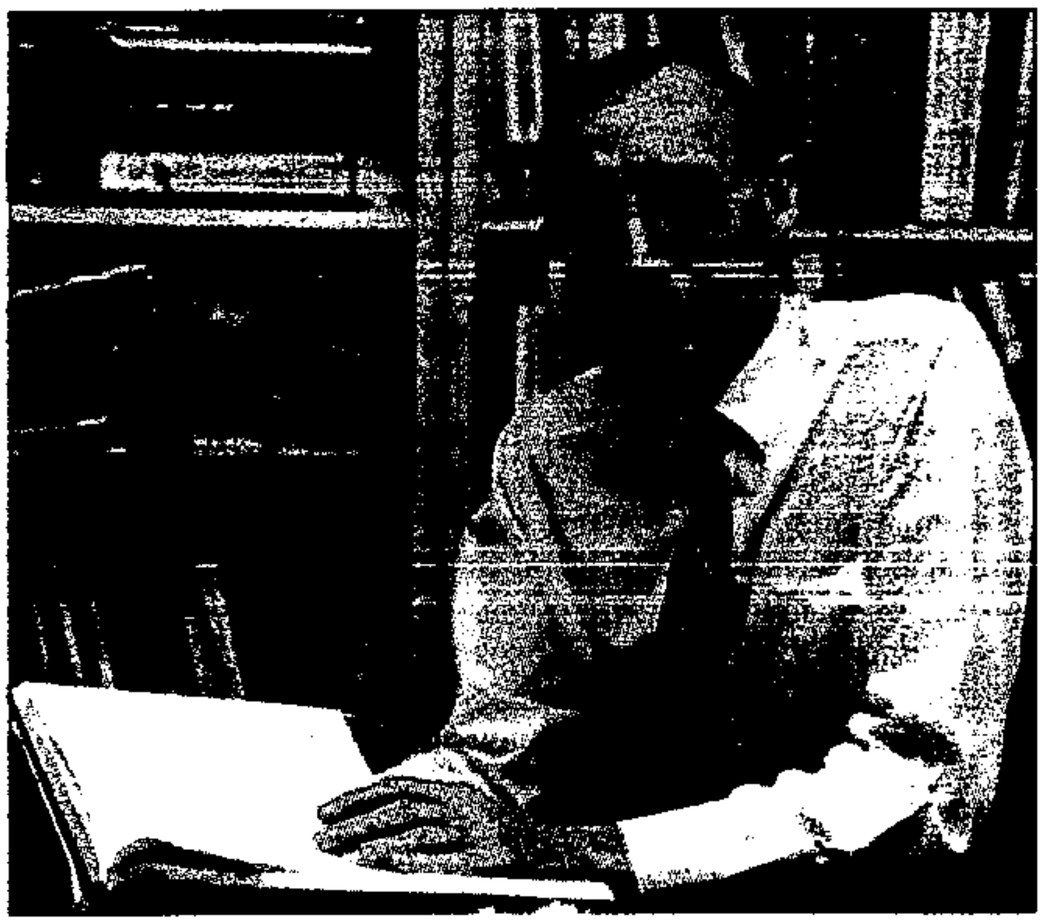
Certainly, for the multi-item and expensive prescription, the proposed fixed fee could mean a saving to the consumer. The cheaper or single item prescription could, however, end up costing far more. But nothing is certain. The proposal states that a pharmacist may calculate his professional fee according to the nature of the service rendered, time and expertise spent delivering the service, the time of day the service is rendered and whether the medicine is readily available.

Says Reekie: "What the pharmacist charges should reflect a price negotiated between him and the customer. Professional fees serve merely to guarantee income for providers, removing incentives for cost containment."

But there are some obvious cost cuts envisaged in the proposal. The wholesaler, who is now able to add 21,21% to the manufacturer's price, would, under the proposed model, be able to add no more than a set 5% to a manufacturer's price. It is not clear whether this is tenable or sustainable, though.

Van Niekerk says drug prices in SA are generally perceived as being "too high" because discounts available in the distribution channel — estimated to be as much as 40% — are not obvious nor necessarily passed on to consumers. He says: "Medical schemes do not necessarily offset discounts received on medicines against expenditure. Instead, discounts are used to offset scheme administration costs." The need for greater transparency in pricing apparently inspired a similar and recent proposal — net pricing (*Business* October 7) — supported by some drug manufacturers, wholesalers and pharmacists. That is being investigated by the Competition Board. The board says justification exists for a statutory restriction on profit earnings by all dispensers. This implies that income from dispensing should be in the form of a professional fee rather than in the form of profit on medicine.

But commentators say the council's present proposal hinges on a plan that would force drug manufacturers to charge a volume related but uniform price only to "legitimate purchasers" — effectively barring manufacturers from giving the large volume unrelated discounts to dispensing doctors that, the council claims, unfairly raises costs for pharmacists.



Reekie ... *onal cartel*

More alarming is the council plan to use its statutory power over all registered pharmacists to force manufacturers to comply with its proposed distribution system (a manufacturing pharmacist must, by law, apply for the registration of medicines.)

Says hospital group Presmed joint MD Rob Speedie: "This is dangerous because, if the council alone can regulate mark-ups, it could increase these at any time without the public knowing." ■

HEALTH — 2

Crippling budget

FM 24/3/95

National health services are bound to suffer this year as health expenditure effectively drops from 10,4% to only 9,6% of State expenditure.

Says Alex van den Heever of the Wits Centre for Health Policy Studies: "While this year's R15,4bn budget appears to represent an aggregate 10% increase on last year's expenditure of R14,1bn, included is an amount of R1,245bn representing RDP carry-through costs for new and specific projects — R680m for free health care, R65m for clinic building and R500m for the primary nutrition programme. This means that existing services will in practice have to make do with around R1bn less than is needed to keep services constant — based on an inflation rate of 6,7%." This effectively means that no allocation has been made for population growth or the extension of services.

A disturbing feature is that while the provinces will be allocated 96% of the budget, no provincial plans are detailed.

Unrealistically, allocations to the provinces will be prioritised to wipe out provincial resource disparities within five years starting with a loading of 30% of the calculated adjustment in the first year — a move that experts say could force the closure of an academic complex in the well resourced province of Gauteng and another in the Western Cape.

It's a formula that appears to be based on a UK model which set about reducing average disparities of around 30% to 10% over 12 years.

An additional R400m has been included in the 1995-1996 RDP vote for transfer to the health departments of Gauteng, Western Cape and Free State to facilitate the substantial transformation required at tertiary and academic hospitals to cope with the move towards strengthening primary health care and shifting the emphasis away from specialised curative hospital-based care."

Apparently KwaZulu-Natal won't be benefiting from this allocation. ■

Generic medicines plan

Political Correspondent

ARG 29/3/95

THE government is considering allowing pharmacists to substitute generic medicines for those specified on doctors' prescriptions.

Minister of Health Nkosazana Zuma told the senate the proposal was being discussed with "role players in the health sector".

(96)

Pharmacists seek go-ahead on generics

KATHRYN STRACHAN

THE Pharmacy Council has called on the Health Ministry to introduce legislation which will permit medicines to be substituted by generics — a move which will lead to a drop in the country's expenditure in this field. (96)

Council registrar Chris van Niekerk said yesterday expenditure on medicines in the SA private sector, expressed as a percentage of total health care costs, was among the highest in the world.

Medicine costs took up more than 30% of total health costs in the private sector, he said, and by encouraging the use of generics — which on average cost half the price of branded medicine — health care costs could be significantly reduced.

While a pharmacist can at present substitute a generic for a prescribed medicine if requested to do so by the patient, the legislation is expected to regulate and strengthen the process.

The council proposed that the Pharmacy Act and the Medicines and Related Substances Control Act be amended to allow for substitution. BD 20/4/95

As well as giving the patient cheaper medicine, the proposal will also enable the pharmacist to lessen the investment cost in duplicating stock.

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Language policy 'not accessible to public'

INGRID SALGADO

THE SABC should not view accuracy of reflection as holding up a mirror to SA's eleven official languages but needed to actively stimulate language development, Education Support Group director Michael Gardiner said yesterday. BD 20/4/95

In a submission before the Independent Broadcasting Authority (IBA), he said the SABC's current language policy was not accessible to the public since it addressed the interests of a minority.

He urged the SABC to synchronise programming, channel planning, dubbing, simulcast and subtitling.

To be accessible, the SABC had to grant the public options on language. News broadcasts, for example, should be available in all eleven languages at some time.

Listeners and viewers should not be confronted with significant differences in quality between productions in different languages. "Pitiful game shows in one language should not be adversely contrasted by slick, well-endowed quiz programmes in another."

Gardiner supported the SABC's participatory role in SA's language destiny, as outlined in its "Value and Vision" document. The SABC should deploy its resources to create opportunity for languages to reach into "unexplored realms", he said.

The SABC will present the document's third draft to the IBA today.

Earlier yesterday, the Afrikaanse Taal en Kultuurvereeniging recommended that broadcasters comply with a local content minimum of 25% during the first year of an effective quota. A minimum of 60% in the long-run would be "ideal".

The SABC needed to provide radio stations in all eleven official languages, while its television licences should be subject to it providing effective and equitable treatment of SA's cultural and language diversity, it said.

☐ The postmaster-general's office has seized the transmitter of a pirate radio station, Radio Triomf, after the IBA last week established that it was operating illegally in the Vereeniging area.

The IBA had referred the matter to the attorney-general's office for prosecution.

Meanwhile, the IBA has approved 16 new community radio licences in Gauteng, Northwest, the Free State and the Eastern Cape. All the stations will broadcast on the FM frequency.

Star 21/4/95 (96)

Pharmacists call for law to allow generics

■ CONSUMER REPORTER

The South African Pharmacy Council, in a bid to cut the soaring costs of medicine, has called on the Health Department to introduce legislation to permit generic substitutions.

Generic substitution can be defined as the act of dispensing a different brand or unbranded medicine by a pharmacist as a substitute for the originally prescribed product.

Chemically, the medicine is the same in the identical dosage form, but is manufactured by companies other than the originator of the drug, after the patent has expired.

In a statement released on Wednesday by the Pharmacy Council, it was said that expenditure on medicines in the South African private sector — expressed as a percentage of total health care costs — is 31%, the highest in the world.

Studies have shown that the private sector wholesaler in some instances pays up to 58 times more for the same medication than the State does on tender.

The statement said generic medicines were registered and had proven quality, safety and efficacy.

Surveys had indicated that the annual price index for branded products was much higher, at 16,7%, than the annual price index of 12,3% for generic products.

Comparative prices of original and generic brands differed from being as low as 18% to a whopping 91%.

A basket of generic products is approaching a level of being only half the price of the original brand basket. The average discount gap is about 46%.

A spokesman for the Medicines Control Council stressed that generic medicines were thoroughly assessed and monitored, that they were of high quality and "strictly comparable with the innovated product".

The council proposed that generic substitution by pharmacists be permitted by amending different sections of the Pharmacy Act and the Medicines and Related Substances Act to ensure, among other things:

■ That medicines which are substituted must be registered with the Medicines Control Council.

■ That the council compiles and updates a list of non-substitute substances which must be published and re-evaluated from time to time and which may not be substituted by the pharmacist.

"Price pressures have resulted in pharmacists being called upon to be more price competitive, yet they have been denied the means by which they can provide more affordable medicine to the public," the spokesman said.

"If this proposal is accepted it will help to give patients cheaper medication."

'Doctors should not profit from medicines'

ARG 16/5/95

MEDICINES Control Council chairman and head of the University of Cape Town's pharmacology department, Professor Peter Folb, has called for the practice of doctors dispensing medicines and making a profit out of it to be banned.

He was speaking at the launch in Cape Town of an updated version of the South African Medicines Formulary compiled by his department in conjunction with the Medical Association of South Africa.

"The mark-up in the price of medicines by the time they reach the public is considerable.

"The practice of dispensing doctors whereby some of them are trading in medicines and making profits should be disallowed.

"The result is that many people cannot afford to pay for their medicines — especially the elderly, the poor and those with chronic illnesses," he said.

Professor Kolb said the medical profession could help by supporting the use of essential, cost-effective medicines and straightforward treatment protocols wherever possible.

A statement said the booklet was a guide to medicines and their generic equivalents, but also contained information ranging from guidelines to sportsmen on drug prescription to up-to-date information on drugs used for treating tuberculosis and malaria, drug prescription for children and the elderly and guidelines for treating hypertension in children. — Sapa.

MEDICAL DRUG COSTS

Don't over-prescribe

Deregulation is essential if the many vested interests are to be kept at bay

(96) FM 19/5/95

Health Minister Nkosazana Zuma should turn to the drug industry as she searches for an affordable and accessible health system. Private-sector drug prices in SA are among the highest in the world, making up around 35% of the total health-care bill. It's also no accident that the pharmaceutical distribution chain is one of the world's most heavily regulated.

The most far-reaching restriction is the prohibition contained in the Pharmacy Act that bars nonpharmacists from owning retail pharmacies, effectively giving professional pharmacists a virtual monopoly (apart from dispensing doctors) over retail drug sales to the public. It's a difficult sanction to justify, since nonpharmacists are owners at every other level of the distribution chain.

It must be pointed out that advocates of ownership deregulation also agree that only a qualified pharmacist or doctor should be allowed to dispense prescription drugs, regardless of who owns a particular outlet.

Certainly the cost implications of this restriction are enormous. Medical aid schemes, private hospitals and big business — all precluded from selling drugs directly to the public — could, arguably, use their bulk buying power to secure large discounts from drug manufacturers. They could, through operating economies of scale, also cut out many of the traditional markups on drugs at the wholesale and retail level, which amount to as much as 100%. Traditionally, 21% is added to the manufacturer's price by the wholesaler and another 50% (of the new total) by the retailer in addition to further charges. Similar reforms in the US and UK cut drug prices in these countries dramatically.

This thinking is also recognised in the Medical Schemes Amendment Act — effective since last January — that empowers schemes to own and run their own pharmacies in order to contain costs. It's an ineffective power since the Pharmacy Act prohibition apparently overrules this concession.

There are sensitive ramifications. Retail pharmacists (around 3 000) fear that their small operations would be put out of business in a deregulated environment by schemes and large department stores such as Pick 'n Pay and Clicks. The Pharmacy Council, which is charged with looking after the public but consists mostly of pharmacists, has thus steadfastly opposed deregulating pharmacy ownership.

But the council is prepared to allow limited nonpharmacist ownership under certain prescribed circumstances — for example, in rural or underserviced areas or places where no pharmacist-owned retail outlet operates.

The trouble is that the council wants the sole right to approve all applications and monitor these ventures continually — claiming for itself an effective veto over entry to the sector by nonpharmacists.

Ironically, of all the professions faced with deregulation, pharmacists have probably been the most enthusiastic about embracing change. With the advent of advertising for the industry, some pharmacists routinely advertise and give discounts of up to 30% on prescription drugs, though other industry players claim that a lack of transparency in pricing often means they inflate the price before "discounting."

Reekie

It's a claim that apparently led the Pharmacy Council earlier this year to propose a new pricing system for the entire industry that would replace mark-ups with a total estimated 26% handling fee — 5% at the wholesale level and 21% at the retail level.

Health Minister Zuma ... *still searching for a fair solution*

The sting, however, is that pharmacists would be able to add a professional fee for their services, which the council suggests would be calculated on a number of subjective criteria that would include the nature of the ailment treated, the time spent administering the treatment and the expertise expended in the treatment. The council suggests a R150 hourly fee as a basis for this calculation. Whether such a proposal could force down prices, however, is not clear. Certainly for the large, multimedicine script, there could be savings. But the single item cheaper prescription could well end up costing more.

The proposal, now before government for consideration, also plans to use the council's professional hold over all pharmacists to force drug manufacturers to charge a single volume-related exit price to "legitimate buyers." It's a proposal that's geared towards ending the special discounts that manufacturers give to dispensing doctors to influence their prescription habits. This practice, claim pharmacists and wholesalers, allows doctors to resell drugs to the wholesaler at lower prices than they are able to secure from manufacturers in the formal distribution channel — ultimately pushing up the cost of drugs in the formal distribution channel (through wholesalers and retail pharmacists.)

Manufacturers are unlikely to accept such a proposal as they are challenging a Competition Board ruling that seeks to achieve a single volume-related exit price. They claim, understandably, that they should be free to market their goods as they see fit.

Anything else that smacks of price controls, or limited drug lists also poses the danger of chasing these large investors out of the country. It must be noted that, several years ago, when the industry faced generic substitution or price controls, it opted for price controls — a choice that could well have been motivated by the fact that controls are difficult to monitor, claims Wits Economics Professor Duncan Reekie. In any case, prices during this controlled period remained unaltered — put differently, there were no savings.

To their credit, pharmacists have also been at the front of the race to extend primary health care by completing special training for contraceptive counselling, blood pressure and cholesterol monitoring and inoculation, services which many pharmacists now offer the community free of charge. A number of enterprising pharmacists have also joined forces to start bulk mail order services that guarantee the public discounts of up to 40% on wholesale prices, effectively cutting back the total distribution markups to only 10%. A growing number of medical aid schemes are also asking users of chronic (long-term) medication to make use of these warehouse-like services that manage to cut costs by cutting frills.

Of course, all of this shows that while deregulating pharmacy ownership may well see some of the numerous small pharmacies close, it doesn't follow that all the pharmacists will be out of work. Most would

Continued on page 34

Continued from page 30

probably find employment with manufacturers, wholesalers and the new retail outlets that schemes and big business would possibly come to dominate. And since the dispensing of prescription drugs would always require the services of a qualified pharmacist, they would be in a good position to negotiate good salaries that could well exceed their present profit margins. The Melamet Report into the financing of private-sector health care, completed last May, suggests that the retail pharmacists are not, in any case, profitable businesses.

States the report: "It is simply inconceivable that about 2 900 retail pharmacists should be able to hold more than 7m scheme members to ransom through their monopoly of drug sales." There is also nothing to stop pharmacists forming larger and more efficient partnerships, thereby holding on to their independence. The Medical Schemes Amendment Act specifically provides for the formation of multidisciplinary health practices (doctors, nurses, physiotherapists, pharmacists) to enable private practitioners to practise managed health care.

Given the doctor's limited pharmacological knowledge (doctors study drugs for only one year, as opposed to the four spent by the pharmacist), such partnerships could only benefit from the experience of the pharmacist, particularly as competition between providers increases the need to find the most cost-effective and appropriate treatment.

Regrettably, though, present professional rules enshrined by the SA Medical & Dental Council (the medical profession's regulator) still prohibit these multidisciplinary practices, a situation that the Competition Board says "leads to conduct that amounts to a restrictive practice that's not in the public interest."

Existing regulations also hinder pharmacists from exploring new options. While numerous studies in recent years have shown that pharmacists, often with little additional training, could treat around 70 common ailments now treated by doctors, government has yet to give them (and qualified nurses) access to higher scheduled medicines.

Pharmacists also argue that routinely being able to substitute branded drugs for cheaper generic equivalents (unless the doctor specifically wants a certain drug) would enable them to dispense the cheapest possible drug. It's a move that drug manufacturers have always opposed, questioning the safety and efficacy of these cheaper substitutes. (State hospitals have used generics safely for the past 30 years, effecting savings estimated at billions of rand.)

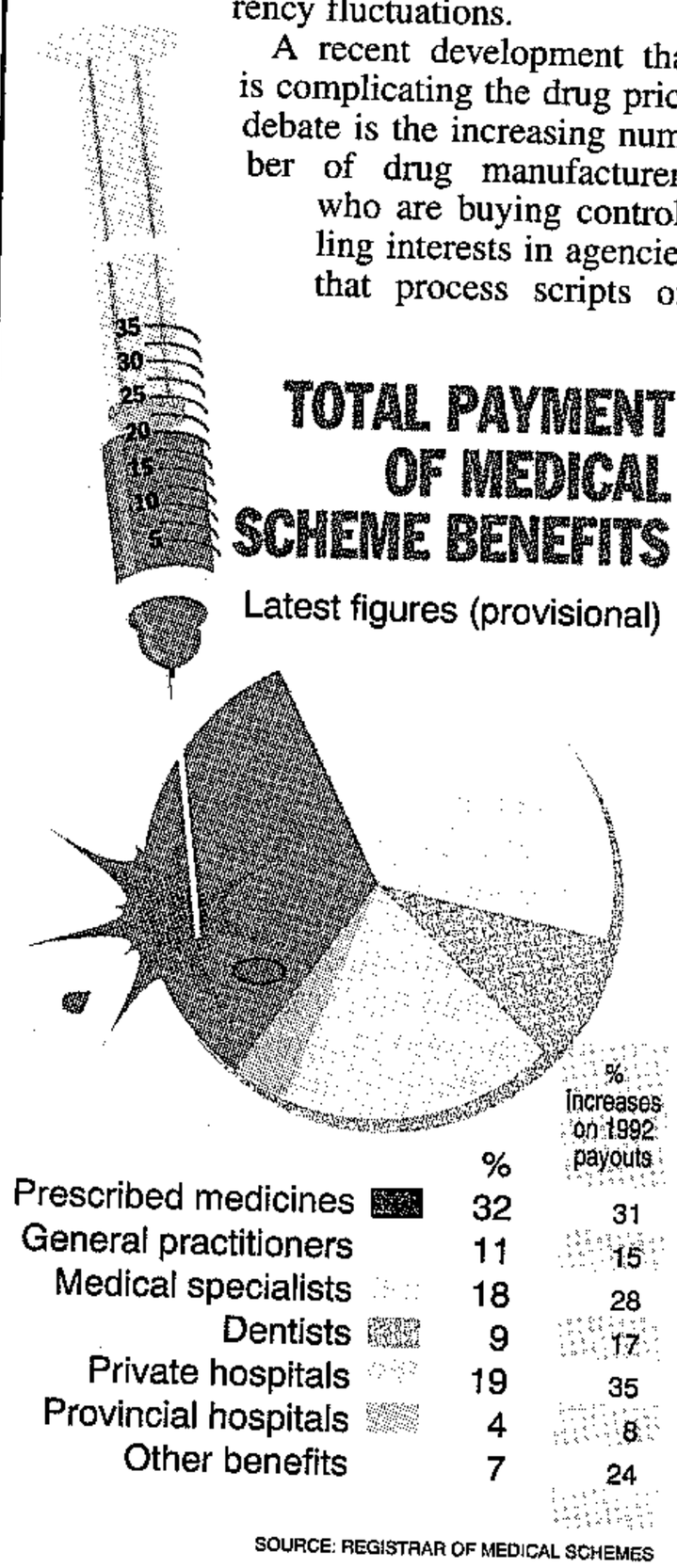
Many of the large international manufacturers have in recent years started their own generic divisions. In practice most simply use different packaging and prices for the same product — which shows what profit margins are at stake and just how seriously they take the international proliferation of generic medicines.

But the generic debate in SA is to some extent academic, since medical schemes are increasingly limiting the amount they will pay for certain drugs. This, in practice, means they will only guarantee payment for the price of the generic drug.

Drug manufacturers also continue to oppose the importation of cheaper but identical drugs from foreign markets, though the Medicines Control Council now permits these imports.

The argument is that this practice would encourage the use of counterfeit drugs. Manufacturers also claim that their factory sale or exit prices are all very similar around the world — notwithstanding currency fluctuations.

A recent development that is complicating the drug price debate is the increasing number of drug manufacturers who are buying controlling interests in agencies that process scripts on behalf of medical schemes.



The most recent aquisition is last week's purchase of a 75% stake in Medikredit (owned by the Pharmaceutical Society of SA) by Glaxo Wellcome and Eli Lilly. Mediscor was purchased by SA Druggists last year. Medikredit and Mediscor process and manage the drug bill for more than 60% of all medical scheme members. Put simply, these agents handle all the administrative work pertaining to the collection and payment of scripts that medical schemes or their administrators would otherwise do.

They also manage the benefits that are paid out to members by negotiating good discounts from retail pharmacies and capping the price that they are prepared to guarantee for a specific drug. In practice, this means they are in a powerful position to influence prescribing and dispensing habits, since the cash-strapped patient is unlikely to ask for a drug that will put him further out of pocket.

For the manufacturer, these acquisitions present a wonderful opportunity to push their products. But Glaxo MD Andrew Witty disagrees. "Our objective is to develop the best disease management protocol for each patient to ensure the best clinical and economic outcomes, ultimately providing an advisory service for managed health-care providers and funders." He says Glaxo products would be used only if they were the most cost-effective.

The Competition Board is investigating these acquisitions. Says the board's Wouter Meyer: "We are concerned that the scheme member will in effect have a limited or no choice of drugs foisted on to him. We are also concerned that these agencies are securing contracts with a limited number of retail pharmacists only, effectively excluding pharmacists who are willing to offer patients even greater discounts than the agency requires."

The board is concerned that for areas where one medical scheme dominates, for example the Eastern Cape or Bloemfontein, this could put nonparticipating pharmacists out of business.

Says Meyer: "These agents need to set clear and objective criteria for pharmacists who want to participate. We certainly don't want to replace one monopoly with another." Witty stresses that Medikredit will continue to welcome any pharmacist who meets its set criteria. "We will also use independent advisers to ensure that the service provided is in the patient's best interests."

Of course, drug manufacturers might well argue that they need this type of selling arrangement to cross-subsidise the State tender system, which makes them supply drugs to the State for as little as 10% of the price paid by the private sector.

Though the value of this cross-subsidy is vast, especially as only around 20% of people are private-sector buyers, a similar arrangement exists in the US, where the State is also the largest single purchaser of drugs and large business is able to muscle massive discounts from manufacturers.

Retail drug prices in that country are, however, often more than 50% cheaper than in SA.

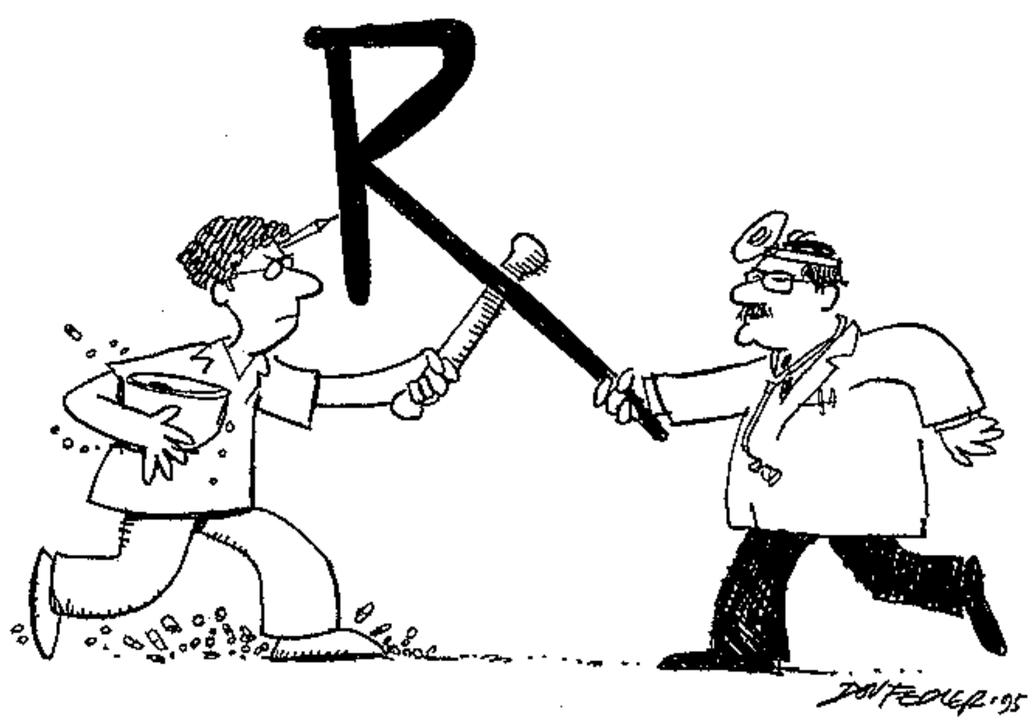
Determining why drug prices are so high in SA is a complex matter. But what is clear is that deregulation is required urgently and extensively if vested interests are to be kept at bay. ■

PHARMACISTS (96) FM 2/6/95

Therapeutic value

Pharmacists have a vital role to play in restraining the health bill and ensuring a healthy population, says Potchefstroom University pharmacy professor Anton Dreyer, who has just completed a major study of the sector.

He says pharmacist-initiated therapy cuts the total health-care bill by as much as R1,16bn a year. Of all the requests received by pharmacists, 78,2% were for the treatment of a condition while only 40,6% were product-related. Says Dreyer: "This supports the view that the pharmacy is often the first port of call for the treatment of, or advice on, self-limiting ailments." His department's research was conducted randomly among the country's estimated 2 900 community pharmacies.



This is good news for retail pharmacists, increasingly under threat from dispensing doctors and advocates of nonpharmacist ownership. Pharmacists, who are able to add as much as 50% to the wholesale price of drugs (marked up by 21% on the manufacturer's price), are accused of being an inefficient link in the distribution chain, despite routine discounting in recent years.

Dreyer claims the outcome of pharmacist-initiated therapy also appears to be good: "While 8,4% of all cases were referred to a doctor, hospital or clinic without the supply of medication, the needs of 74,8% of the patients were satisfied with an over-the-counter product and 12,6% were referred to a doctor if initial treatment was not effective."

He adds that among recipients of over-the-counter treatments 62,9% reported a satisfactory improvement, 30,1% some improvement and 4,5% experienced no change. The average cost of these treatments is R27,26.

Dreyer also points to diagnostic screening tests increasingly offered by pharmacists. "Only 39,6% are charged to the patient, at an average charge of R4,57 per test. Of these tests 81,8% were for blood pressure, glucose and cholesterol."

Prescription intervention by the pharmacist remains a vital professional function, claims Dreyer. US studies show that 50% of adverse drug reactions in any year could have been avoided — cutting the health bill by an estimated US$3,5bn.

Dreyer's investigation also points fingers at doctors' apparently inadequate pharmacological knowledge. For 3 124 prescriptions dispensed by 135 pharmacies, 3,9% of prescriptions had to be stopped completely while 48,1% had to be changed before dispensing. Some 7,5% of prescribing errors or omissions requiring intervention involved allergies and similar reactions to one or more prescribed drugs, while 8,6% of interventions were for drug-to-drug reactions.

If pharmacists are to make progress towards accessible health care for the public, they need to be given access to higher scheduled medicines — for example, antibiotics for the treatment of common respiratory infections.

It's a recommendation that was made in 1980 by the Browne Report and one that is endorsed by international practice. While pharmacists have in recent years undergone special training to extend their diagnostic capabilities, government still has to allow them (and nurses) access to these higher scheduled medicines.

Doctor opposition is believed to be a stumbling block but greater access to scheduled drugs for pharmacists could well be the pill that sweetens pharmacy-ownership deregulation for pharmacists. ■

Top pharmacy groups gear up for the future

(96) BD 8/6/95

HILARY JOFFE

FUTURE government health policy is likely to increase pressure on drug companies to contain costs. But it should also bring more people into the health care system, so enlarging the market.

Managements of the major JSE-listed pharmaceutical groups await details of the ministry of health's new policy thinking with interest, but not apparent anxiety. All three groups — Adcock Ingram, Premier Pharmaceuticals and SA Druggists — have been actively positioning themselves for growth in a changed health care environment.

Specifically, they have been increasing their investments in the manufacture and distribution of generic drugs — cheaper copies of research-based "ethical" drugs whose patents have lapsed — and of over-the-counter (OTC) medicines. These are expected to be the fastest growing markets in future. They are so already because of changes in the public and particularly the private health sectors in the past few years.

Generic substitution has been used in public hospitals for more than 20 years, but a study by Wits University's Centre for the Study of Health Policy (CSHP) in 1992 found generic medicines made up only 12% of the private pharmaceuticals market. Growth in the generics market has since accelerated, to 25% of the private market last year, according to SAD. The growth is in line with international trends.

However it is also because of efforts by the medical aid schemes to contain drug costs, particularly since they were deregulated at the beginning of 1994. That has helped: the medicines price index in December showed price increases for the year at 6,8% compared to an inflation level of about 9%.

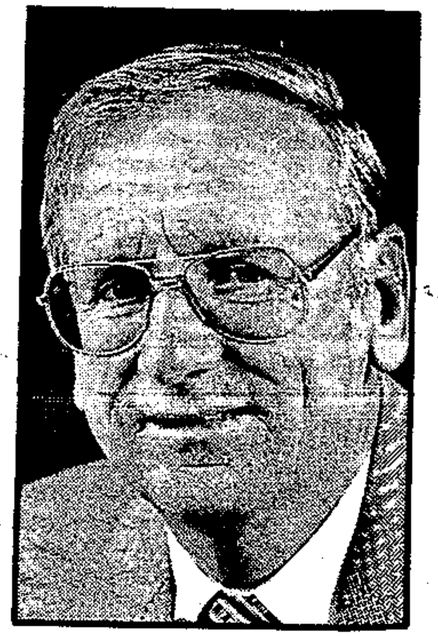
Competition in the generics market has increased, with some of the multinational drug companies (the manufacturers of most of the ethical drugs) moving in as well. Rivalry could become fierce if the government moves to introduce an "essential drugs list" of the kind used in several other countries. A recent CSHP study by Bada Pharasi, now pharmaceuticals director in the health ministry, noted SA's public sector hospitals currently have 2 700 drugs on the central purchase list. This compares with 329 in Mexico, 618 in Zimbabwe and 1 100 in Norway. The study recommends an essential public sector drugs list.

Expansion and acquisition strategies among the local big three during the past two years have focused on generics and OTC drugs. Premier Group subsidiary Prempharm's acquisitions include Laser, Leppin, Pharmatec, Salters and Zurich, all in generics or OTC medicines. Where pharmaceuticals contributed 49% of Prempharm's turnover during the 1994 financial year, the acquisitions have raised this to the "high 50s", according to Prempharm financial director Hymie Shapiro.

OTC products make up the largest part of this, followed by generics: exposure to ethical drugs is minimal. The pharmaceutical division increased profitability in the six months to end-March despite rationalisation costs resulting from the acquisitions, helping the group to a 23% earnings increase. It is in the process of upgrading its manufacturing facilities and has entered into a joint venture with a black business group to manufacture generics, targetted at the public sector market.

CE Phil Nortier says the group is looking at further expansion opportunities in the OTC and generic areas and in consumer healthcare, for example patent medicines, personal health care and beauty. Further acquisitions could be single products or suitable companies.

Malbak's SAD has, as one analyst



BODLEY

puts it, "done a good PR job on its product portfolio", which has contributed to the share's rerating over the past year, putting it ahead of Adcock, which used to be the blue chip of the industry. SAD has the largest share of the generics market, and in a presentation last year CE Peter Beningfield cited figures showing the group to be the cheapest dose supplier, with a 12% share of the pharmaceuticals market by value but 25% by volume.

SAD's strategy is towards managed health care, so, for example, expanding into medical aid claims administration. It has also taken a significant share (the analyst estimates 35%) of the market for intravenous drips which was previously virtually monopolised by Adcock, and is expanding its health care and international divisions.

The exposure of CG Smith's Adcock to "ethical" drugs has been seen by the JSE as a disadvantage. But management believes it is well positioned to take advantage of expected growth in generics: it holds third position in the total market (public and private sector combined) and second in the private market. Generics account for 30% of the group turnover (including intravenous solutions), its Adco range of generics is growing by 30% annually. Also, the group has increased investment in new product development as well as marketing.

But CE Don Bodley stresses that patented new drugs (ethicals) will still have a place. Generics are based on research which can be 20 or more years old (patents are in force for 20 years) and, says Bodley, "in many instances generics have been superseded by more advanced therapies which save costs to the health care system by reducing or eliminating the need for expensive hospitalisation and surgery and improving the patient's quality of life". Adcock last year bought into branded generics company Vesta Medicines and entered an alliance with multinational Eli Lilly.

Bodley sees the group's strength as its broad portfolio of products. He says the medical aids' continued focus on cost reduction will result in more patients turning to responsible self-medication, in line with world trends. Adcock's consumer health products division holds second position in the self-medication market with strong leadership positions in some categories.

The group also expects to maintain its dominant share of the intravenous drip market. In financial 1994 this division (critical care) contributed 44% of operating profits, pharmaceuticals 32% and the self-medication/consumer division 17%. The group expects a more balanced contribution to profits from its divisions in coming years.

Both SAD and Adcock have sizeable distribution arms (Prempharm is not in distribution), which contribute large turnovers but little profit. This has been a difficult and turbulent area of the industry. One analyst describes distribution as very fragmented and suggests government may look at an industry-wide solution. Another possibility a new health dispensation might offer the private pharmaceutical groups is an enhanced role in distribution for the public health sector.

Bodley notes distribution could play a strategic role in future in supplying hospitals, clinics and doctors. Pharasi's study recommends the continuation of the current system of central drugs procurement for the public sector but calls for urgent investigation of the involvement of private companies in warehousing and distribution, because of the loss of stock through theft and expiry at state depots and hospitals.

Bodley believes a viable private sector will remain, especially given its well-developed infrastructure, and more people will be absorbed into the medical aid system. In this he is probably reflecting the views of much of the industry.

The pharmaceutical groups' shares are trading on price earnings ratios of 16-17 on the JSE. That is below the more high-flying ratings of more cyclical stocks, which benefit from huge earnings increases as economic recovery gains pace, but still implies a healthy respect by investors. The market view is that, whatever the Health Ministry has in store for the drug companies, they will continue to make profits. The companies are attempting to adapt to an uncertain future to justify that view.

PARLEY VIEW

Our enormous drug bill

WM 23-29/6/95 (96)

Pat Sidley

THE average private sector general practioner prescribes medicines that are spectacularly more expensive — sometimes as much as 700 percent — than do their colleagues in the public sector using an essential drugs list.

And drugs bought by the state are much more expensive than overseas drugs — despite the pharmaceutical companies' claim that the "low" state tender prices have to be subsidised by the high private sector prices.

This, and other startling information about South Africa's huge drugs bill, is contained in a report commissioned by the National Health Inquiry and tabled this week.

The report notes that the prices through Comed (the body which runs the state tender system of buying drugs) were around 23 percent higher than international prices for essential drugs.

A drug used to treat tapeworm, for example, was bought by Comed at a price 33 times higher than the international price.

The report states that despite the fact that Comed bought drugs worth R1,3-billion each year, it could provide no information on drug use.

Calculating the effects of the introduction of an essential drugs list, the report estimates that the pharmaceutical industry could loose up to 12 percent of its turnover if the private sector is given access to cheaper drugs.

It also calculates that private pharmacies may lose R13 000 each per year (a total of R46-million over the 3 500 pharmacies), with dispensing doctors each losing R10 000 a year.

The report recommends that international competition be allowed in the state tender system.

Pharmacies' monopoly under fire

(96)

ST 25/6/95

By CIARAN RYAN

SUPERMARKET chains are preparing a full-scale attack on the retail pharmacy industry following recommendations to the government to end pharmacists' monopoly over the retailing of prescription medicines.

The Broomberg-Shisana Committee of Inquiry into National Health Insurance, which published its report this week, has proposed sweeping changes to the industry in a drive to cut medicine and health care costs.

Rene de Wet, joint managing director at Pick 'n Pay, says his group will enter the pharmacy business as soon as allowed.

"We will phase in pharmacies at our 147 stores countrywide, starting with the newer stores ... The objective is to offer the services of a typical family pharmacy, concentrating on delivering prescription drugs at a low price."

Trevor Honneysett, chief executive of Clicks, says that if the recommendations translate into deregulation, Clicks will enter the pharmacy business. "But we have had a lot of false starts in the past, so we need to see whether this report will actually allow us to do that."

OK Bazaars is understood to be considering the lease of space to pharmacists, rather than open its own pharmacy retail chain.

Ivan Kotze, executive director of the Pharmaceutical Society of South Africa, doubts whether supermarket pharmacies will be viable in the light of the recommendation that the state will be responsible for bulk purchasing of the Essential Drug List, covering 90% to 95% of common illnesses.

Mr Kotze says the plan removes profit motive by requiring all pharmacies to purchase essential drugs at state tender prices.

"If the motive for supermarkets entering this business is profit, then I am opposed to it. If, however, their motive is to advance the cause of universal health care, then I support it where there are no pharmaceutical services."

The entry of supermarkets into the pharmacy retail market poses a threat to many of the country's 3 000 pharmacies, particularly in dispensing drugs not on the Essential Drug List.

About half of South Africa's 10 000 doctors dispense their own medicines which they buy at prices below those of pharmacies. The removal of this lucrative revenue from doctors may prompt many to emigrate, or form group practices employing a pharmacist to dispense medicines.

"The pharmacist and doctor accredited by the state will now have to keep two sets of stock — one for the public and one for the private sector," says Kobus Nel, marketing director at SA Druggists, the country's largest producer of generic drugs.

"While this plan is an improvement on the Deeble option announced earlier this year, it is still too socialistic. I don't believe the state has the distribution capacity required to deliver what this plan promises."

Manufacturers of branded drugs such as Glaxo are awaiting publication of the Essential Drug List to determine what its impact will be.

WATCHING BRIEF . . . Clicks' Trevor Honneysett, who says the chain will enter the trade if recommendations translate into deregulation

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(96)

Fluoride in water for our teeth

Star 17/7/95 (96)

CHEAP AND ACCESSIBLE
A new policy to prevent one of South Africa's most common health problems today – tooth decay – is on the cards. **GLENDA DANIELS reports.**

Despite all the controversy, adjusting the natural fluoride content of domestic water may very well be the cheapest way of ensuring that a large number of people achieve the greatest protection against tooth decay, according to specialists.

Tooth decay is still one of the most common health problems in South Africa and one of the ways to reduce its incidence is to introduce fluoride into water, says Dr Gonda Perez, the recently appointed chairperson of the Water Fluoridation Committee, set up by Health Minister Dr Nkosazana Zuma.

Perez, who is also the registrar in the Department of Community Dentistry at the University of the Witwatersrand, says that by the end of this year, the committee hopes to have all the systems in place so that the new policy on fluoridation can be implemented.

Where this is not possible because of a lack of access or because of economies of scale, fluoride toothpaste will be made available to needy communities.

"We want to reduce the pain and suffering that people experience due to decay. We want to take preventative measures rather than have to deal with dental problems," says Perez.

According to Perez, adjusted levels of fluoride in water supplies have been proven, over several decades, to be effective against tooth decay in many parts of the world. It is estimated that over 800 million people worldwide benefit from flouride. Water fluoridation is available to 210 million, fluoride toothpaste is used by 450 million, and 50 million people use fluoride salt.

Toothy view ... fluoride in water will help stop tooth decay, says Dr Gonda Perez. New government policy will make oral health accessible to all and might be implemented after the end of this year.

PICTURE: NATASHA PINCUS

Some reasons for fluoridation are: It is the least expensive way to ensure that a large number of people achieve the greatest gain in protection against tooth decay; a reduction of disease burden is likely to be seen within two years of the enactment of the policy, and workdays lost due to decay will be regained. Another benefit is that lower socio-economic groups and especially women and children will gain from the new policy.

Apart from protecting against tooth decay, fluoride has been used in recent years for the treatment of osteoporosis. There is some evidence that the long-term consumption of water-borne fluoride may prevent its development. This is of particular importance to women who suffer from loss of bone mass density as they get older.

Perez says that in South Africa there is an uneven distribution of fluoride in water. In some areas, for instance the Northern Cape and the North West province, there is too much fluoride and people suffer from discolouration or "brown spots" on their teeth. In urban areas, such as Gauteng, and coastal areas such as Durban and the Western Cape, there is underfluoridation.

What about the risks of fluoridation? Perez says that there has been no conclusive study proving any health risk.

She says that while some people have wrongly maligned fluoride as a cancer culprit, most studies have shown that there has been no difference in the incidence of cancer in fluoridated or unfluoridated areas.

Perez says that the debate about whether children should take fluoride supplements has not been concluded.

Her personal feeling is not to prescribe fluoride supplementation to children as a general rule. She says that it should be decided on an individual basis.

"You would look at the parents' dental status and the child's diet."

But she warns against giving children too many sweets and sweet drinks, especially just before they go to sleep.

"Their teeth should be wiped after they have a fruit juice to prevent decay. It is also preferable to give them water if they go to sleep with a bottle."

Perez also warns against the six-monthly checkup generally recommended by dentists. They are not necessary and it is "more about lining the dentists' pockets than anything else".

A once-a -year visit to a dentist is enough, she says. To promote healthy teeth and gums, a good brush of your teeth at least once a day, ideally twice a day, is required.

In the meantime, tooth decay is rampant, but Perez and her team are confident that the introduction of fluoride will reduce dental problems by at least 50 %.

"We want to reduce the pain and suffering that people experience due to decay. We want to take preventative measures rather than have to deal with dental problems"

The state of tooth decay in SA

A recent study in a peri-urban informal settlement recorded peoples' experiences of acute health problems: "tooth and mouth" were the third highest complaint.

Fifteen year olds have almost as much tooth decay as 12-year-olds. At 20, the number of teeth that people have lost is between 40 % and 73%, which is very high when compared to the World Health Organisation (WHO) goals for these age groups. In some communities more than half the adult population over the age of 35 have no teeth at all.

With increasing urbanisation, changing dietary habits, increased sugar consumption and lack of exposure to optimal flourides for the bulk of the population, the level of tooth decay experienced by South Africans is increasing.

Useful to know:

Fluoride – a naturally occurring substance found in water – but all the water we drink do not contain high enough levels to protect from tooth decay.

Water fluoridation – the regulation of fluoride in public water supplies.

Fluorosis – is a mottling of the teeth, which in some cases, can be unsightly.

Defluoridation – is the reduction of fluoride in water supplies where the natural levels are too high.

* By the Health Policy Co-Ordinating Unit's *A Policy to Prevent Tooth Decay in South Africa*, compiled by Professor C P Owen for the fluoridation sub-committee.

TOMORROW:
Three homeowners are dreading the arrival of the rainy summer months, as waterproofing contractors have failed to fix their leaky roofs.

New training for pharmacists

(96) CT 11/8/95

PRETORIA: New training courses would enable pharmacists to offer more primary health care services, the South African Pharmaceutical Council said yesterday.

In a statement, council registrar Mr Chris van Niekerk said new regulations published in the Government Gazette would enable pharmacists to register their completion of the training.

Govt price control plan will not overlook in-store pharmacies

BD 30/11/95 (96) (~~135~~)

Jacqueline Zaina

GOVERNMENT's proposal to implement price controls in the pharmaceutical industry would not preclude major retailers opening in-store pharmacies, said health department deputy director-general of policy and planning Ayanda Ntsaluba this week.

The response follows Pick 'n Pay MD Gareth Ackerman's assertion that government's positioning on the matter was inconsistent. The group had plans for in-store pharmacies, but their implementation would depend on the position adopted by government, he said.

Ackerman said initial government recommendations included the opening up of the pharmacy sector to non-pharmacists, but the latest report on a national health system suggested that government intended to nationalise control of the drug industry and retain a monopoly on purchasing.

Pick 'n Pay had a number of contingency plans for the development of in-store pharmacies, from company-owned outlets to franchises in terms of which pharmacists could rent space in-store, but would only enter the pharmaceutical market if it proved to be a viable business proposition.

It was unclear whether pharmacies would be profitable at all and this would depend on whether it would be possible to negotiate prices at manufacturer level. Deals on purchasing commissions were a primary source of profit, he said.

Ntsaluba said government proposals, including generic substitution, removal of the profit margin at retail level and the introduction of price controls at manufacturer and wholesaler level were not contrary to the opening up of pharmacy ownership to retailers.

The move which would require amendments to the Pharmacy Act would probably be introduced early next year, said Ntsabula.

Chief director of drug registration, regulation and procurement Bada Pharasi confirmed that OK Stores was in the process of discussions with the health department regarding its proposal to establish clinics in its stores.

The group was interested in facilitating the development of health care facilities, including pharmacies, doctors' practices and state drug dispensaries on its premises.

Clicks was also awaiting the change in legislation before it went ahead with any plans for pharmacies, said store development and merchandising director Chris Roesstorff.

He said that the chain was based on the US drugstore concept, except at this point it was not allowed to dispense medicines.

The group had obtained exclusive rights to market UK company Boots Pharmaceutical's No 7 range of cosmetics in SA. Boots already manufactures and markets a number of leading branded pharmaceutical products in the local market.

Drug discounting system to change

(96) BD 22/12/95

Jacqueline Zaina

THE retail pharmacy industry plans to scrap its controversial discounting policy, conceding that the chaotic pricing structure has led to high medical costs.

The Pharmaceutical Society of SA said yesterday the current system — where individual pharmacists bump up prices to gain a profit and then offer a discount — had hit margins but failed to reduce medicine costs.

A new pricing system, proposed by the society's national executive committee, would remunerate pharmacists at the rate of about R120 an hour.

Society president Cecil Abramson said the fee would effectively remove the profit motive in the sale of prescription medicines, and redefine the pharmacist's role to include patient counselling and monitoring to justify the fee.

The system would cut medicine prices by increasing pricing transparency and contributing to the rational usage of drugs.

The move represents a major concession to government, which has criticised pharmacists for their profit-driven prescription policies.

Abramson said the new pricing would be based on a non-discriminatory exit price from the manufacturer, who would also be required to stop sampling to doctors.

At wholesale level, the mark-up of 21% would be reduced to 8-10%, to cover basic costs. The patient price would be the base price plus the distribution fee, pharmacist's holding and administrative costs, plus the professional fee.

Abramson said medical aids would pay the cost price of medicine as well as a 10-15% margin for the pharmacist's investment in stockholding.

Link Pharmacies CE Mike Dobson said the industry was seeking greater recognition for bulk purchases as part of submissions to government for a single exit price on drugs.

The Pharmaceutical Manufacturer's Association said it welcomed initiatives to bring down costs, but favoured pharmacy ownership deregulation to allow competition to determine prices.

CE Mirryena Deeb said manufacturers would rather face competition to supply at the right price than have to deal with government intervention.

She said it appeared that government proposals set out in its latest report, Towards a National Health System, had been influenced by the pharmacy industry's new pricing structure.

But she warned the report's main conclusions — extending the essential drug list to the private sector, price controls and mandatory generic substitution — would amount to nationalisation by stealth and push up drug prices in the public sector.

The proposals could threaten the 17 000 skilled jobs in the pharmaceutical industry.

Pharmaceutical regulation bid defended

BD 11/1/96 (96)

Jacqueline Zaina

GOVERNMENT could have a case for regulating the pharmaceutical industry with its history of discriminatory pricing and profit fixing, competition board chairman Pierre Brooks intimated yesterday.

The industry last month claimed government's proposals to regulate drug prices would contravene competition policy. The board would make recommendations to government on the industry's behalf, but Brooks said it was generally accepted if market forces had failed to have the desired effect in a particular industry, regulation was justified.

The industry had behaved contrary to economic principles, with escalating prices despite high levels of competition in the pharmaceutical sector.

The industry lodged a complaint with the board concerning proposals contained in the government's health policy document, Towards a National Health System. The move followed fears that Health Minister Nkosazana Zuma would have proposals passed without further consultation with the major players.

The Pharmaceutical Manufacturer's Association, National Association of Pharmaceutical Manufacturers and SA Association of Pharmacists in Industry felt the proposals for price controls, generic substitution and extension of the drug list to the private sector amounted to nationalisation of the industry.

Essential drugs list is significant step in health care revamp

KATHRYN STRACHAN (96)

BD 28/3/96

ON APRIL 1 the health department takes the most significant step in its restructuring programme when it introduces an essential drugs list for state primary health centres.

By setting up the list, which streamlines an existing range of about 3 000 drugs to a package of about 400, government will ensure the cost of drugs in primary clinics will be greatly reduced and that outlying centres will be assured of a reliable supply. Of all the department's initiatives, the new list holds the most promise for improving health services.

But it will have far-reaching effects and the pharmaceutical industry is concerned that the list policy might be extended to private sector health care.

National Association of Pharmaceutical Manufacturers executive director Barney Sachs says such a move would have "potentially disastrous consequences".

While the pharmaceutical industry accepts implementation of the list in state clinics, the potential for it to be applied in the private sector has sparked controversy and been the subject of many behind-the-scenes meetings.

While the health department has shelved its proposals to extend the list to the private sector, whether they are revived later will depend on the private sector's ability to contain spiralling medicine costs. Between the lines, the department is saying that unless the private sector takes steps to reduce medicine costs, it will have to intervene.

But pharmaceutical multinational Glaxo's CEO Andrew Whittey believes health department intervention will not be necessary as the drug manufacturing industry is already rapidly changing the trajectory of price increases. In the past year, six of the 10 multinationals have increased their prices by 6%, below the annual increase in the consumer price index, he says. Glaxo managed to get by with a 3% hike in medicine prices.

The high medicine bill is partly a function of price, says Whittey, but much is due to using wrong drugs and to over-utilisation. For this reason, his firm is developing a system to help doctors and pharmacists prescribe the appropriate medicines.

"In three years, private sector health care will be completely different," he says. Plans to extend exports to about 25 countries will enable pharmaceutical manufacturers to lower prices.

Whittey says it makes sense to rationalise the range of drugs in the public sector, but warns that a private sector essential drugs list is illogical. At present, the private sector buys drugs at about six to 15 times the price offered to the public sector, and extending the list to the private sector would upset this balance. The private sector would no longer be subsidising the public sector and the low prices offered to the state would end.

"This would not be a sensible move to make at a time when government should be diverting wealth," says Whittey.

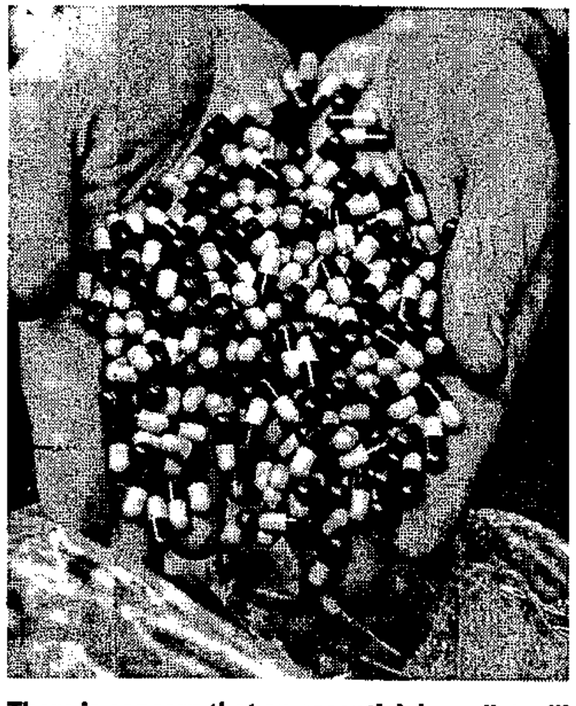
Representative Association of Medical Schemes (Rams) executive director Reg Magennis says an essential drugs list will work only in a system of private sector managed health care where contracts between the medical schemes and doctors are more specific than at present, and there is agreement on the medicines used and treatment guidelines. The private health sector is moving towards such managed care, he says, and the list could be a useful element in this system.

In the domain of the public sector, the list could have a big effect on medical schemes. If patients found the list met their requirements, they could choose to drop their medical aid and go to the clinics where medicines were dispensed free. However, if the list was too "basic", they would stick with the medical schemes.

Rams is taking the approach of waiting to see the response of patients to the new list.

Another effect of the essential drugs list on medical schemes could be that if the public sector succeeds in dramatically cutting prices, pharmaceutical manufacturers could seek to increase prices to the private sector even further to recover losses.

And pharmaceutical manufacturers would be tempted to drop their public sector prices to rock-bottom to ensure their products were included on the list.



There is concern that an essential drugs list will be applied to the private sector.

"The essential drugs list will need time to grow and evolve," says Sachs. "Changes to the list will have to be made along the way, and local pharmaceutical manufacturers, too, will have to learn to adjust to the changing health needs if they are to survive."

Trade and industry department chemical and applied industries director David Walwyn is encouraged by the new drug policy's aim of promoting local manufacturing. There is a long way to go in terms of producing a viable SA pharmaceutical manufacturing industry, he says, but the new policy offers two factors which are keys to assisting the process.

Firstly, the list provides a focus for the local industry which allows it to concentrate on improving the quality of selected drugs. Secondly, a selective procurement policy is a stated objective of the new drugs policy. This 15% price preference for local manufacturers means they get the tender even if their product is more expensive than an imported product.

Walwyn says the multinational manufacturers have complained that there is too much regulation in the new system. And he does not believe the health department will stop at implementing a drugs list in the public sector.

He says the local pharmaceutical industry does not generate a lot of profit or revenue in terms of taxes. Because the cost of raw materials is high, little value is added in the local manufacturing process, so the profits are low.

Dr Des Theron, medical officer for the Bo-Karoo district in Northern Cape, says rural doctors are enthusiatic about the new plan's promise to ensure medicines are delivered to outlying clinics.

When the nearest pharmacy or supplier is 400km away, reliable distribution is central to health delivery, he says, and a single essential drugs list package will be far easier to deliver than ordering thousands of different drugs from various points.

The list will also boost the primary health care nurse practitioner scheme, he says. In the new health system, nurse practitioners are being trained to a level where they can screen patients on their arrival at the health centre. They diagnose and treat the patients they can deal with, and refer the rest to the doctor — thereby reducing the heavy workload of rural doctors.

And with a streamlined list of about 400 drugs, rather than the previous 3 000, the nurse practitioner will have a better grasp of available drugs.

District councils will also save a lot as they will now get medicines directly through the province at the state price, as opposed to the previous tender system involving dealing directly with separate pharmaceutical manufacturers.

In general, doctors have welcomed the concept, but they are reserving judgment until they know how it will work in practice, the accompanying treatment guidelines, and exactly what drugs are on the list. Among items under scrutiny will be medicines used by traditional healers, which will be investigated for safety and quality with a view to incorporating them in the health system in the future.

Govt to prohibit doctors and pharmacies from marking up medicine

(96) (183)

Kathryn Strachan

GOVERNMENT will reduce the price of medicines dramatically on July 1 when it introduces legislation to prohibit private doctors and pharmacy retailers from placing a mark-up on the price of medicines they dispense.

The prohibition, to be enforced by the health department, will be effective on July 1, from when consumers will pay only a small dispensing fee for medicines on top of the wholesale price. The dispensing fee will be covered by medical aids. Doctors will still charge consulting fees.

The Medicines Control Council was preparing regulations to compel doctors to prescribe generic medicines. This would have a major effect on the cost to consumers, said health department director of medical schemes, supplies and services, Precious Matsoso.

While pneumonia could be treated with the brand product Amoxil at a cost of R94, the generic equivalent would cost R4,11.

Health ministry special adviser Ian Roberts said the dispensing fee was still being negotiated between doctors, pharmacists and the department.

Matsoso said it was important that doctors' consulting fees were improved in tandem with the new plan.

Roberts said the department was also exploring the most rapid means of effecting new drug legislation in order to implement this plan.

The new drug policy would limit the number of dispensing licences given to doctors. Private doctors would have to prove their competency to dispense, and would be licensed only if there was no pharmacist in their vicinity.

Roberts said medicine prices in SA's private sector were among the highest in the world. The health department was obliged to ensure all people had access to affordable health care whether they used public or private health facilities.

He said the new drug policy addressed the entire medicine chain, and all levels including medical aids would be affected.

Pharmaceutical consultant Mark Hyman said pharmaceutical retailers would have to restructure their operations completely in order to survive.

Each month 2% of retailers closed down, and unless changes were made, 25% to 30% of retailers might have to close in the next year.

Matsoso said that if all these plans did not succeed in achieving savings in the private sector, the department would need to look at applying the essential drug list — which would be introduced in state clinics next week — to the private sector.

ARG 2/4/96

R1-bn drugs stolen

Zuma says tough curbs in prospect to deter fraud

The Argus Correspondent

DURBAN. – The Department of Health and Welfare is probing the loss of scheduled drugs estimated at least R1 billion, and may use codes to deter further thefts, Health Minister Nkosazana Zuma has announced.

Dr Zuma also indicated yesterday that the European Union's R14 million ploughed into *Sarafina 2* might be returned if it made a formal request.

Interviewed during a tour of several clinics in rural communities in KwaZulu-Natal, she said drug losses had cost the pharmaceutical industry R1 billion over a three-year period from 1993 to last year.

They were believed to be mainly due to fraud and pilfering.

"Anyone found with drugs they shouldn't have should be prosecuted," Dr Zuma said. "Manufacturers should mark the drugs so that it is clear whether the drug is destined for the private sector or public sector."

Regional Health Ministry spokesman Dave McGlew said: "I believe that the police are also investigating the theft of drugs, which has become serious in the health sector. New, stricter regulations will no doubt put an end to the racket."

Asked to comment on reports that the EU was demanding its R14 million back after the *Sarafina 2* débâcle, Dr Zuma said if the request was made formally, she saw no reason why it should not be granted.

"I will not debate the matter through the Press ... if the request is formal then I don't see a reason why it should not be given back."

She added that the play was reaching its intended target and that young people in Soweto had taken to it.

Dr Zuma, together with provincial Health Minister Zweli Mkhize, visited clinics in Mthandeni, Mvutshini and Sivananda which will undergo upgrading shortly.

Soweto patients try out free clinics

Kathryn Strachan

BD 2/4/96

THERE was an atmosphere of festivity as primary health clinics in Soweto opened their doors yesterday and treated all who came free of charge.

Patients flooded into the clinics on the first day of government's free primary health care for all — but clinics reported that despite the surge, the first day had gone smoothly.

"People are very happy they have been given this opportunity to get free health care," said chief matron Theodora Mohadi, who supervises all the clinics in Soweto.

The consulting room in Soweto's Zola clinic was packed, but matron Vivien Makedana said extra nurses and doctors had come in to deal with the flood.

At Chiwela clinic patients were in for a wait because they had all come before the clinic doors had opened, said matron Dorothy Mosaka. By 2.30pm the clinic had seen about 600 patients, and by 3pm there was just a trickle of patients coming through.

Some matrons said nurses had complained about being overworked yesterday, but the additional staff who had been brought in had helped

Gauteng deputy director-general of health Eric Buch said he was impressed by the commitment and enthusiasm of the nurses — as well as by their questions about how the plan would be sustained.

See Page 19

Limit on drugs faced if private sector fails to curb its prices

Kathryn Strachan

BD 2/4/96

(96)

GOVERNMENT has stated that unless reforms unveiled this week succeed in bringing down medicine prices in the private sector, it will have to intervene by limiting the number of drugs available.

The health department shelved an earlier proposal to extend the policy of an essential drugs list — which was introduced into state clinics yesterday — to the private sector.

Whether it later gets revived depends on the private sector's ability to contain medicine costs. The list limits the existing range of about 3 000 drugs, used by general practitioners and clinics, to a set package of about 200 drugs.

National Association of Pharmaceutical Manufacturers executive director Barney Sachs has said that applying the essential drugs list to the private sector would have "potentially disastrous consequences".

It was therefore in the interests of pharmaceutical manufacturers, wholesalers, retailers and private doctors to make sure that the measures unveiled this week succeeded in bringing prices down.

The department said at the weekend it planned to reduce the price of medicines dramatically on July 1 by introducing legislation to prohibit mark-ups by private doctors and pharmacy retailers..

Consumers will then pay only a small dispensing fee in addition to the wholesale price. The department was also introducing regulations which compelled doctors to prescribe cheaper generic medicines.

Representative Association of Medical Schemes executive director Declan Brennan welcomed the move, but warned of the dangers of "merely shifting costs" and called for consultation with all stakeholders to ensure that the consumer benefited.

He said that in SA 30% of medical aid is spent on medicines, compared with between 8 and 10% in the UK and the US.

Health ministry special adviser Ian Roberts said the drug policy unveiled this week addressed the entire medicine chain, and all levels including medical aids would be affected.

Pharmaceutical retailers have supported the move as they believe a dispensing fee will give them greater security than a system of mark-ups.

Pharmaceutical Society's Brian Walpole said the medical-aid schemes imposed a discount on mark-up, and the retailer came out with very little. The retail sector is struggling and an average of 2% are closing down each month.

There is also pressure on pharmacists to play a role in primary health care rather than simply surviving on retail profits.

The department's moves are aimed at creating transparency along the entire chain, so that customers will be able to see the exact mark-up on a product at each level.

Trade and Industry Department chemical and applied industries director David Walwyn says there is a long way to go in creating a viable pharmaceutical manufacturing industry. Because the cost of raw materials was high, very little profit was made.

Health department director of medical schemes, supplies and services Precious Matsoso said the high cost of raw materials for subsidiaries of multinationals was in many cases due to "transfer pricing" — the local subsidiary charged an excessive price for raw materials, leading to low profits locally.

She said that although trade and industry had removed the import duties on raw materials for pharmaceuticals last year, this step had not resulted in a lowering of prices.

Pharmacists welcome dispensing policy

ARG 18/4/96 (96)

The new National Drug Policy for South Africa proposes that pharmacists and dispensing doctors who will have to qualify for dispensing on an annual basis, charge a professional fee for dispensing medicine. This, rather than relying on dispensing for profit at high mark-ups, is a revamp in the health care system that is to be strongly welcomed, says general manager for Roche Consumer Health, Richard Westcott.

Westcott says the multiple spin-offs implied by this new legislation, which have come into effect – besides making medicine more affordable for the consumer – promises to benefit many groups.

"It is no secret that the profit motive in the dispensing of medicine has been a major factor in the creation of a chaotic health system.

"A strong objective of the new National Drug Policy is that dispensing of medicine and the provision of health care should be done on the basis that the accessibility and affordability to health care of the community is improved – and not simply as a business strategy to make more money. This is an important and welcome new emphasis, that will have far reaching benefits towards reducing health-care costs."

Westcott says a professional fee for pharmacists is likely to stabilise the income of community pharmacies. He points out that currently members of the pharmacy profession are researching how these fees work in other countries, for example Canada, and the impact of the system on the industry in South Africa.

"Pharmacists - who have been pushed to the periphery of health care in recent years with the rapid growth of dispensing doctors – will not be able to rely on profits from medicines that they dispense. At present, a pharmacist's daily income is heavily dependent on the type of medicines he dispenses and the total value of a prescription. Many pharmacists have also been forced to stimulate non-health care categories – glassware, pool chemicals and jewellery – of their business as a result of the drop in dispensing business.

"With the introduction of a fixed fee, a retail pharmacist's business will be stabilised. His role as a centre of preventive health care, I believe, will become much more evident.

"I expect more consumers will return to filling their scripts at pharmacies – as dispensing doctors do not find dispensing medicine as financially attractive and close their dispensing or fail to qualify for licenses under the new drug policy. The pharmacist can expect to fill higher numbers of prescriptions. This is obviously also good news for medical aids, who will not be paying out as much for dispensed medicines."

Wescott says that community pharmacies have an important role to play as primary health care centres, especially as advisories on preventative strategies for good health.

"For pharmacists to fill a powerful, clear role in health care in South Africa, it is recognised by the profession that they've got to get out front and counsel. Notably, pharmacy assistants also have an important role as counsellors. Presently Roche Consumer Health is running a programme wherein we have 7 000 assistants participating in educational courses.

"In our discussions with pharmacists, they have expressed a major need for more pharmacy-based education on nutrition and vitamins. Not enough consumers have adequate knowledge of the benefits of a sound nutrition.

"The quality of dietary intake is a vital aspect of preventative health care. So if more South Africans learn about the basis of a healthy lifestyle, many lifestyle diseases can be prevented," says Wescott.

'Perverse' drug discounting practice to stop

Star 2/5/96 (96)

End to 'off-invoice bonusing' should bring down cost of pharmaceuticals

By Janine Simon
Medical Correspondent

Pharmaceutical manufacturers have fallen in line with the Health Ministry's moves to curb drug prices and have finally stopped one of the industry's most inflationary practices: giving dispensing doctors and pharmacies "bonuses" in the form of free prescription medicines.

The Pharmaceutical Manufacturers' Association of SA (PMA) announced this week that members had agreed to stop "off-invoice bonusing" from the end of April, and would open their books to independent auditors if there were allegations that the agreement had been breached.

The move had been approved by the Competition Board and would help to contain health care costs, and end a number of potentially unethical practices, it said in a statement.

The PMA, which represents SA's multinational, research-based pharmaceutical companies, said off-invoice bonusing had contributed significantly to a steep rise in the use of prescription medicine and overall health care inflation in recent years.

"For consumers, any practice that encourages unnecessary prescribing is potentially harmful, since patients seldom question the decisions and prescribing habits of their practitioners," it said.

The move was also expected to ensure price transparency throughout the distribution chain, so that discounts given by manufacturers did in fact reach the consumer.

The agreement showed the industry's commitment to the competition-law principle that a seller should not unfairly discriminate between the same class of buyer.

However, this principle allowed lawful price differentiation, by which a seller could determine price according to factors such as volumes and terms of payment.

The PMA was, accordingly, revising its marketing and practice codes in collaboration with the Competition Board, to a form which would encourage the self-regulation of the industry.

The announcement was welcomed by Dr Ian Roberts, special adviser to the minister of health, who said bonusing was one of the perverse incentives pushing up prices in the health sector.

In some companies, up to a third of drugs were bonused, and prices on other products were raised to cover the costs. Scrapping the practice would therefore allow for significant price reductions, he said.

It would also help to combat the grey market in pharmaceuticals as bonus drugs were not invoiced or declared, and so added to the problem of tracking goods stolen from pharmacies and state hospitals.

Drug firms cut bonuses to doctors

(96)

OWN CORRESPONDENT

CT 2/5/96

JOHANNESBURG: Pharmaceutical manufacturers have fallen in line with the Health Ministry's moves to curb drug prices and have finally stopped one of the industry's most inflationary practices: Giving dispensing doctors "bonuses" in the form of free prescription medicines.

The Pharmaceutical Manufacturers Association of South Africa (PMA) said its members had agreed to stop "off-invoice bonusing" from the end of last month.

The move was approved by the Competition Board and would help contain health care costs, and end a number of potentially unethical practices, it said.

The PMA, which represents South Africa's multinational, research-based pharmaceutical companies, said off-invoice bonusing had "contributed significantly" to a steep rise in the use of prescription medicine and health care inflation in recent years.

"For consumers, any practice that encourages unnecessary prescribing is potentially harmful, since patients seldom question the decisions and prescribing habits of their practitioners," it said.

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Pharmaceutical body moves to cut medicine costs

BD 3/5/96 (96)

Kathryn Strachan

IN A move expected to cut high medicine costs to the public, the Pharmaceutical Manufacturers' Association (PMA) has agreed to stop giving out free medicines, particularly to dispensing doctors.

The practice of giving free promotional medicines to doctors has in recent years contributed significantly to a steep rise in the use of prescription medicines and overall health care inflation.

Doctors often prescribed these promotional medicines unnecessarily because they could in turn charge the patient for the medicine, and make 100% profit.

"For consumers, any practice that encourages unnecessary prescribing is potentially harmful, particularly since patients seldom question the medical decisions and prescribing habits of their practitioners," PMA CEO Mirryena Deeb said. She said the ban would help to contain health care costs and end unethical practices.

The move was also expected to contribute towards greater price transparency throughout the distribution chain, ensuring that discounts given by manufacturers do in fact reach the consumer.

Through this move, the PMA aimed to encourage the self-regulation of the industry.

Earlier this year, the health department warned the industry that unless it took steps to lower medicine costs to the public, the state would intervene with far more drastic measures.

Deeb said the PMA's agreement was part of a general commitment by the industry to abide by the competition law principle. According to this principle it is unfair to have discriminatory pricing between the same level of buyer, such as a pharmacist and a doctor.

However, lawful price differentiation does allow factors such as volume, terms of payment and creditworthiness to be taken into account in determining prices.

Pharmacists attack mail order medicines

(96) BD 22/5/96

Jacqueline Zaina

DEMANDS by some medical aid schemes that members buy certain medicines by mail order posed serious health risks, the Pharmaceutical Society of SA warned yesterday.

Society executive director Ivan Kotze said a survey among pharmacists had shown mail order medicines for illnesses such as epilepsy, diabetes or blood pressure often arrived late or not at all.

Medical schemes often insist customers buy such drugs through mail order, which enables mail order companies to negotiate bulk purchases with manufacturers to bring down retail costs.

But of the 147 pharmacists the society surveyed, 44 rated the risk associated with such ordering as dangerous, with 49 rating it highly risky.

Kotze said the society would now commission a one-year study and an independent risk rating to back up its initial findings.

"This is the most serious aspect of our concerns about mail order pharmacy, because in treating chronic illnesses like epilepsy, diabetes or blood pressure problems, continuity in the medicine supply is vital," Kotze said.

"Medicine is not a normal commodity and we don't think that the health risk involved in postal supply can be justified by the few cents which it saves the customer."

There was also no control over patients buying mail order medicines and other drugs, such as cold remedies, over the counter which could interact.

Medical aid administrator Pharmaceutical Benefit Management marketing director Rodney Cowlin said mail order pharmacies were able to discount medicines by 30-35%, compared to the 15-30% offered by retail pharmacists.

But the old relationship with the community pharmacist, which had facilitated the monitoring of the patient's drug consumption, had been lost.

The company was not against mail order supply, but recognised there could be difficulties relating to it. However, the decision lay with individual medical aid schemes, which often gave patients the option of where to source their medicine.

The Representative Association of Medical Aid Schemes said it was concerned, but would await definitive findings.

Executive director Declan Brennan said the mail order sector did not rely only on postal distribution, but made extensive use of courier services. Patients suffering from chronic ailments knew weeks in advance to order additional medication, which meant suppliers had sufficient time to deliver, he said.

Draft law tightens the rein on medicine costs

(96)

ST 2/6/96

By PAT SIDLEY

THE government is drafting new laws to control medicine prices and regulate the pharmaceutical industry.

It is also changing many of the regulations governing the medicines industry and the public's access to drugs.

The changes are intended to ensure that there are legal mechanisms in place to bring down the price of medicines if the pharmaceutical and related industries do not drop them voluntarily.

The proposed changes to the law form part of a wider National Health Act being drafted in government and provincial health circles.

It will cover almost all aspects of health, although private health sector issues are likely to fall under separate legislation.

The draft National Health Act envisages wide powers to regulate the drugs industry, including powers of search and seizure.

If passed, it will empower pharmacists to substitute expensive brand name medicines with generics. Under current law, only doctors may decide what drugs are dispensed.

The proposed law also places a responsibility on the state health authorities to get the best deal when buying drugs and, where possible, to buy generics, particularly from local manufacturers.

This is in line with the Drug Policy launched by the Department of Health earlier this year.

The proposals also lay down a legal framework for the Essential Drug List — under which only basic, inexpensive, safe and effective drugs may be used in state health facilities.

Practices in the health industry which the government wants to stop include pharmaceutical companies giving free drug samples to doctors and lavishing gifts on them during product launches.

Among issues in the proposed law likely to prove controversial is a provision for abortions in state hospitals.

Other proposals:

- Give patients a legal right to information about their health and medical treatment, and the right to have somebody explain matters to them fully;
- Ensure the right to privacy for minor patients older than 14;
- Give patients the right to proper treatment;
- Ensure informed consent for procedures cannot be overridden by a contract signed on admission to hospital, a widespread practice at private hospitals; and
- Set up a complaints procedure for patients if something goes wrong.

Doctors, who have been left out of draft discussions, are likely to have some strong views.

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Call for strong purgative medicine

Head of Pharmaceutical Manufacturers' Association calls for rapid action and prosecution of offenders in the industry

(96) Star 19/6/96

By David Robbins
Health Writer

The best laid plans by the national Department of Health to clean up South Africa's pharmaceutical industry and lower the price of medicines could be scuppered if firm action is not taken against those who break the rules.

This is the forthright view of Mike Norris, president of the Pharmaceutical Manufacturers' Association (PMA), who believes that a special prosecution system for pharmaceutical malpractices needs to be set up, and that prosecutions should be made to stick.

"Doctors and pharmacists, as well as manufacturers and wholesalers, all need to be subject to much stricter policing, and those who break the rules should be prosecuted. There should be no hesitation, as there obviously is now."

Norris gives three recent examples of highly dubious or downright illegal actions which have elicited no action from the relevant authorities.

■ A doctor writes to a pharmaceutical manufacturer (Norris shows me the letter) threatening to prescribe no more of that manufacturer's products unless free samples of one particular product are forthcoming. "Is this an ethical problem or isn't it?" Norris asks. "Yet to date the South African Medical and Dental Council has declined to take any action."

■ A pharmacist supplies drugs to a patient at full cost even though the drug packaging has been stamped "sample – not for sale". "Some manufacturers are now marking samples given to doctors in this way. Clearly, this one has found its way out of the consulting rooms and on to the shelves of a commercial pharmacy. The pharmacist concerned (again Norris shows the correspondence) was merely given a warning by his professional association. But was a doctor also involved?"

■ One recently stolen batch of pharmaceuticals valued at R1-million and taken from the manufacturer's premises has been identified (by batch number) on the open market. Wittingly or unwittingly, pharmaceutical wholesalers and retailers are trading in stolen goods. But there's no word of any prosecutions, says Norris.

The litany of problems is lengthy. Manufacturers have been accused of offering bonuses in the form of uninvoiced pharmaceutical stock, especially to dispensing doctors. This has encouraged the practice of round-tripping where doctors are able to acquire more drugs than they need and to channel the surplus back into the market, often at enormous profits.

This practice, along with widespread theft from the public sector, has done nothing to contain the price of medicines in South Africa, and there is also the very real fear that stolen or round-tripped drugs are not properly stored. This could mean the sale to an unwitting public of high priced drugs that have lost much of their efficacy.

"The PMA welcomes the Government's endeavours to clean up this undesirable situation. We, the manufacturers, have recently agreed to end the practice of off-invoice bonusing. In fact, some association members are phasing out the giving of samples to doctors altogether. But this alone won't stop the spiral of theft. Estimates are that the stolen-drugs sector of the market is worth between R500-million and a R1-billion each year." says Norris.

THYS DULLAART

Concerned ... Mike Norris wants to see pharmaceutical industry cleaned up.

Norris outlines the fortunes of one expensive drug which is supplied to the state and to the private sector market in considerable quantities. It is stolen from state warehouses and hospitals and released into the highly lucrative private sector market, resulting in many millions of rands of easy profit.

"The government stock was marked as such, on the boxes in which the drug was distributed, in a bid to discourage theft. But the thieves simply repacked the drugs. In fact, the manufacturer in question even found the printer who was reprinting the packaging, but the police did not take the matter further.

"So the manufacturer printed with ink-jet the words – government pack: not for resale – on to the actual aluminium blisters in which the individual tablets were packed. But the thieves removed this telltale information with a specially formulated solvent.

"Then the manufacturers actually embossed the batch numbers into the aluminium blisters. The thieves then stole the drugs at source, before they could be marked as government stock."

But Norris insists that controls at government hospitals and warehouses must be stepped up. "Theft, poor stock control and inefficient administration at state institutions still accounts for the lion's share of stolen pharmaceuticals. No amount of control at the manufacturing level can alter this."

He points, also, to the cost implications for manufacturers. The anti-theft printing and embossing has undoubtedly added to the cost without adding anything to the value of products, while manufacturers' security systems are becoming more and more sophisticated – and expensive.

"We have been criticised for the high manufacturing costs of pharmaceutical products, and the Government is still talking about parallel importing and international tendering as initiatives to reduce these costs. But in my view they will do nothing to solve the basic problem. If Government can't effectively police the theft of existing products, think what a mess it's going to be with the situation confused by a multitude of imported ones."

Other planned Government interventions, such as the outlawing of dispensing doctors, the removal of the profit motive from pharmacists by paying instead a dispensing and product holding fee, and even the introduction of an essential drugs list, would not help, to discourage the dishonesty in the industry at present, Norris says.

"The same applies to the Government suggestion to use a vericode system to identify every pack of pharmaceutical product in the country. It's feasible, provided everyone in the distribution chain keeps the necessary records. It'll add to the basic cost of medicine. Nevertheless, I know that members of the PMA would probably be prepared to contribute to the system. But will it solve the problem? It's one thing – and a good thing – to be able to identify stolen goods, but quite another to catch the thief."

It is for this reason that Norris has called for the establishment of a special pharmaceutical prosecutions body.

"This is what the Government should be doing. Unless people are speedily prosecuted for dishonesty, and unless the guilty are firmly punished, no amount of reform will fundamentally rectify the situation. And people within the distribution chain all need to play their part."

ARG 21/6/96

Chemists seek recognition under new act

Labour Reporter

(96)

THE South African Association of Community Pharmacies (SAACP), which has 1 800 members, wants recognition under the new Labour Relations Act (LRA) as the employer organisation for the retail pharmacy sector.

The LRA, which will be implemented on August 1, aims to promote collective bargaining in broad sectors of the economy.

The SAACP said it wanted to be recognised as a retail sector employer organisation to ensure it was not "lumped together with other members of the chemical industry".

Job crisis at medical nerve centre of the Cape

(96) (85)

■ The Health Department has stepped in over a crisis at the Cape Medical Depot — the nerve centre for the delivery of drugs to over 500 health facilities in the Western and Northern Cape. ARG 29/6/96

ADELE BALETA
Staff Reporter

THE Health Department has launched an urgent investigation into the creation of posts at the Cape Medical Depot, which has a week-long backlog in the delivery of drugs to more than 500 health facilities in the Western and Northern Cape.

The depot supplies medicines to tertiary and secondary hospitals, community health centres, clinics and district surgeons in both provinces.

In an interview with SATURDAY Argus several disgruntled staff members said heavier demands had been placed on the depot since the announcement of free healthcare in 1994, while at the same time posts had been frozen.

One staffer said: "We cannot get the drugs out fast enough without help. We receive faxes on a regular basis from various health outlets in the Peninsula and from the rural areas saying they are out of stock and unless we help them they will have to close down."

A major concern was supplying drugs to the rural areas because it took longer to get them to their destination.

But Fareed Abdullah, the Western Cape Health Department's chief director of healthcare, said there appeared to be a need for more staff and that the creation of posts, particularly for storekeepers, would be investigated in the next three weeks.

He said staff from other areas would be seconded in the meantime to help out with the backlog, which had already been reduced from 10 days to seven.

"The lack of staff has been exacerbated by a week-long strike about three weeks ago," he said.

Dr Abdullah said that while surgical supplies were on track, the delivery of drugs was behind.

He added that a mechanism was in place to deal with emergency cases where, for example, facilities or district surgeons ran out of drugs.

Vivian Titus, principal pharmacist of the Community Health Services Organisation in the Western Cape which handles the needs of community health centres (former day hospitals), said the situation was critical.

"We are running out of stock and there is not a community health centre that is unaffected," he said. "I get phone calls every day and I want to appeal to people to be tolerant."

Bill Munro, chief pharmacist of the Northern Cape and stationed in Kimberley, said outlets throughout the provinces had been affected and deliveries were up to three weeks behind.

"We are completely dependent on the depot in Cape Town and are not getting sticks up here.

"[illegible] Upington to Upington, Upington to Prieska, Prieska to Kimberley to De Aar to Prieska, everywhere."

He said a feasibility study was being conducted on setting up a depot in the Northern Cape.

Staff at the depot in Chiappini Street said the demand for their services began increasing when in July 1994 all children under the age of six and pregnant mothers were given free medical care.

This was followed with the announcement on April 1 that the depot would be responsible for the delivery of medicines to 200 old-age homes.

The pressure was increased again with the instruction that from May 1 free medicine would be given to all members of families whose annual income was less than R35 000.

"More clinics and day hospitals have been built and that means more facilities to handle.

"The bottom line is that the number of orders have trebled since May 1 and yet the posts have been frozen," an employee said.

Employees said they needed more pharmacists, storekeepers and general assistants.

New pharmacy system to be tested at Jo'burg Hospital

(96)(188) Star 2/7/96

By Janine Simon
Medical Correspondent

A pharmacy offering prescription drugs and primary health-care services is to open in the Johannesburg Hospital as a research collaboration between Wits University's department of pharmacy and the private sector.

The services will be available to university students and staff, and later, the public.

The pharmacy has been donated and stocked by the private sector. It will be run by a pharmacist, but used to train pharmacy students, and evaluate drug-pricing structures and models of group practice health care, said head of department Professor Indres Moodley.

"We're entering unknown territory, but we're looking for the best possible model of health care at the interface between the private and public sectors. It could change the way health care is delivered in this country," he said.

The pharmacy's start-up donation of prescription drugs includes 250 medications for common ailments specified on the Basic Medicines List, a comprehensive list of medications based on the Essential Drugs List.

These will be sold to the public initially on the model of cost plus 20%, to analyse the viability of one of the Department of Health's options on medicine price structures: that medicines have a standard point-of-entry price and a fee for the pharmacist's service, Moodley said.

Funds from medicine sales will be channelled into a university administered account to pay for research, he said.

The pharmacy will also examine the effectiveness of a group-based primary health care practice operating out of a pharmacy.

On the first model being evaluated, the pharmacy would run a practice comprising a primary health-care nurse, pharmacist, general practitioner, x-ray and laboratory services.

Patients will be able to consult a nurse or general practitioner and get a basic prescription drug for about R30.

Those who the nurses feel need further attention will be referred to the GP, Moodley said.

The pharmacy will be located in a former Medical Research Council laboratory in the department of paediatrics on Hospital Street, and is expected to be up and running by next month.

R24m grant for new drugs policy

CT 15/7/96 (96)

ANEEZ SALIE
HEALTH WRITER

LOCAL efforts to get to grips with the lucrative, billion-rand pharmaceutical industry have received international support.

Health Minister Dr Nkosazana Zuma said at the weekend on her return from a visit to Canada and the United Kingdom that the World Health Organisation (WHO) and Britain had agreed to provide expertise and a R24-million grant to help South Africa sort out its drugs policy.

In terms of current practice pharmaceutical companies have virtual carte blanche in supplying any number and quantity of drugs to state institutions, albeit on tender. A monopoly ensures that cheaper, generic equivalents are often not supplied. Only about three, huge multinationals control the entire R2-bn industry.

Sensitivity around the issue surfaced recently in the wake of the Sarafina 2 scandal when President Nelson Mandela rejected widespread demands for Zuma's dismissal, citing powerful forces ranged against the government's National Health Plan, of which a vital part was an Essential Drugs List (EDL). Such forces were apparently bent on getting rid of Zuma, who has championed an EDL.

Mandela warned however, that drug companies should be tackled with caution because they controlled the supply of vital drugs.

The list would contain only about 300 drugs which state health facilities may purchase only at set, discount prices. The government is also looking at cheaper supplies from countries previously excluded because of sanctions, such as India.

On her return, Zuma said the British government would also provide R12,5m to teach health trainers at provincial and national levels.

International grant for SA drug policy

(96) BD 15/7/96

HEALTH Minister Nkosazana Zuma said on Saturday the UK and the World Health Organisation had agreed to provide expertise and a £3,5m grant to help SA in its recently launched drug policy.

"The project will discuss the distribution, pricing and provision of pharmaceuticals and help South Africa's understanding of this process," she said on arrival from her visit to Canada and the UK.

The UK government had agreed to provide £1,8m for a training project to pass on skills to medical practitioners at provincial and national level.

She had also discussed exchange programmes between SA, Canada and the UK.

"A specific programme to train nurses in eye care has been established to enable nurses to train others in improved health care.

"They will receive a grant covering all their expenses and tuition," Zuma said. — Sapa.

Govt doctors get pay-levelling pact

(96)

PRETORIA — An agreement had been reached on uniform pay for doctors and dentists in the public sector, the health department said at the weekend.

Doctors would also be paid a commuted rate of overtime based on average estimates of overtime worked by each category, and on-call overtime pay, the department said after a meeting between the director-general of health and provincial heads of the department this week.

"The aim of the meeting was to conclude an agreement on a uniform nationwide mechanism for remuneration of all categories of medical doctors and dentists working in the public sector. The department believes that the new total package for doctors in the public sector is very competitive and will attract many doctors, especially South Africans, to serve in the public health sector," the department said.

It was reviewing hospitals which qualified for the recruitment allowance to recruit doctors into rural and underserved areas. Hospitals in the former TBVC states were excluded from this allowance. — Sapa.

BD 22/7/96

Dispensing doctors oppose regulation

By Janine Simon
Medical Correspondent

Doctors have lashed out at the Department of Health's recently gazetted plans to regulate dispensing doctors, saying the minister is exercising authoritarian control over the profession.

The proposed regulations stipulate that doctors and dentists may only dispense medicines after being authorised by the director general for health, and passing a course in dispensing prescribed by the South African Medical and Dental Council in consultation with the SA Pharmacy Council.

The proposed regulations were published for comment in the Government Gazette of July 12.

The notice states that the minister intends to make the changes to the Medicines Control Act in three months' time – on October 12 – and invites interested parties to submit comment by August 20.

"This challenges my professional right to do something I'm already trained to do," said Dr Dennis Dyer, chairman of the South African Managed Care Coalition. "The minister is able to change the act without putting it before Parliament."

Dr Morgan Chetty, chairman of the Medical Association of South Africa's standing committee on general practice, said the proposed legislation would destroy an infrastructure serving 3 million people.

Declan Brennan, executive director of the Representative Association of Medical Aids, said more warning had been expected from the minister. They were concerned about the impact on dispensing doctors and their patients, and the practicalities of implementing the examination system.

Bada Pharasi, Chief Director of Registration, Regulation and Procurement said yesterday the location and condition of applicants' premises would be taken into consideration.

"Authorisation depends on people having taken the exam and their facilities passing the inspection," he said.

(96) Star 24/7/96

Doctors choke on new rules for selling medicines

(96)

By PAT SIDLEY

ST 28/7/96

SWEEPING changes are being made to the ways in which medicines are prescribed, dispensed and marketed.

The government has gazetted details of its intention to:

- Compel doctors to use only generic names on prescriptions, enabling pharmacists to dispense a cheaper alternative when there is one;
- Enforce a licensing system for doctors, nurses and others who dispense drugs — which will cut down the number of dispensing doctors but pave the way for more ethical and clinically appropriate dispensing; and
- Supply patient-friendly leaflets with medicines, giving dosage requirements, side-effects and warnings.

The government intends to allow a short period for comment on the proposals, which have been on the cards for two years.

With any modifications agreed to, these regulations and others already drafted will be promulgated shortly in terms of the Medicines and Related Substances Control Act.

The proposed measures include curtailing some ethically dubious practices such as pharmaceutical companies giving large quantities of free or hugely discounted drugs to doctors who sell them at a profit.

These and other inducements are used to encourage doctors to prescribe certain products.

The regulations are being resisted by many pharmaceutical companies and doctors.

The private practice committee of the Medical Association of South Africa has decided to lobby against the measures, along with other organisations representing dispensing doctors.

The Medical and Dental Practitioners Association, which represents black doctors, many of whom dispense, says that the measures hark back to the apartheid past. Other groupings are raising funds to pay for an attempt to challenge the proposals in court.

Doctors unite against new controls

(96) Star 7/8/96

By Janine Simon
Medical Correspondent

Doctors and trade unions have united against health department attempts to clamp down on dispensing doctors, and may take the issue to the Constitutional Court.

Regulations on new controls for dispensing doctors were gazetted on July 12, and although comment was invited, Health Minister Nkosazana Zuma has the power to change the Medicines Control Act and implement the changes on October 12.

The new regulations enable the health department to stop private doctors close to pharmacies from dispensing; this, doctors say, autocratically robs them of their right to dispense.

An alliance of groups representing about 18 000 doctors will meet in Port Elizabeth at the weekend to formulate alternative proposals to the regulations, according to Dr Joe Maelane, chairman of the South African Medical and Dental Practitioners Association (SAMDP).

But Dr Ernst Snyman, of the National Association of Independent Practitioners Associations (Naipa), said he believed the Government would go ahead despite objections.

"The talk is all window dressing. We are already considering taking the matter to the Constitutional Court, as pharmacists are the only ones who will benefit from these changes."

Trade unions, medical, dental and consumer organisations united for the first time last week to voice their objections to the planned changes at a meeting with the health department, Maelane said.

Included at the meeting were the Medical Association of South Africa (Masa), Naipa, the SAMDP, the South African Managed Care Coalition, the National Education, Health and Allied Workers' Union, the Congress of South African Students, ANC and PAC doctors groups and the Black Consumer Union.

In a statement this week Masa threw its weight behind opposition to the regulations, saying they contradicted the objective of making affordable health care more accessible.

Regulations appeared to be aimed at paying patients and private doctors only, said Dr Ivan McCusker chairman of Masa's health policy committee.

Chief director of National Health Systems Ray Mabope said yesterday that the regulations would go ahead, but that, based on the content of the objections, the director-general of health would ask the minister to discuss the possibility of changes.

Joint funeral for three Tembisa stampede victims

Star 7/8/96

By Mike Masipa

The service for three of the 16 people killed in the stampede at Tembisa station will be held at the Mehlareng Royal Beech Nut Stadium in the township on Saturday.

Spokesman for the Tembisa disaster committee, Bheki Khumalo, appealed to Tembisa residents to exercise maximum restraint in the runup to the funeral service.

He said the rest of the victims would be buried in various areas across the country.

Khumalo said police had assured funeral organisers there would be a massive security presence throughout the service.

But he cautioned against the use of private security companies "because the situation was still tense".

"We don't anticipate the presence of security companies during the service. Their presence might lead to emotions heating in the light of last week's incident," said Khumalo.

The use of electronic batons by security guards during a ticket search is widely believed to have caused the stampede that led to the death of the 16 people and injuried 64 others.

Organisers appeal to mourners to remain calm

Meanwhile, Metro Rail has temporarily withdrawn the services of the two private security companies involved in the carnage last Wednesday.

Metro spokesman Honey Mateya said the security companies had been withdrawn from the Tembisa line until the findings of a commission of inquiry into the stampede, currently sitting at Kempton Park, were available.

The commission is scheduled to report to Transport Minister Mac Maharaj by August 15.

He also announced that train services, suspended after the tragedy, would resume their normal schedules in Tembisa today.

Khumalo said the decision to resume services was reached at a meeting attended by Metro Rail, local ANC and PAC leadership, commuter associations and community organisations.

Speaking at the joint media briefing, Mateya said Monday's meeting also decided on setting up train commuter forums in Tembisa to improve facilities and to address "the culture of non payment".

400 pharmacies to be primary health centres

(96)

MEDICAL CORRESPONDENT

STAR 8/8/96

A group of retail pharmacies will be going head-to-head with doctors, particularly those dispensing medicines, when it converts its more than 400 pharmacies nationwide into private, primary health care centres.

The move, which will see doctors and nurses working inside pharmacies, was announced yesterday by Pharma Clinic, a new division of Medhold Ltd, a listed medical supply company.

Pharma Clinic is aiming for its primary health care (PHC) centres to offer a low-cost private health care package to the 14 million South Africans who are employed but have no medical cover, said general manager Mark Hyman.

The move comes in anticipation of mandatory health care for all employees and the urgent need to extend primary health care services.

It is also a reaction to a range of factors threatening the viability of retail pharmacies in their current form.

Pharmacies' gross profit and turnover were being badly affected by discounting on prescriptions, courier prescribing, dispensing and trading doctors, and lack of direction from within the industry, Hyman said.

Clinics to be staffed by nurses

Proposed changes to drug-pricing structures, and changes to the Pharmacy Act which would pave the way for retail chains to open dispensaries, would also negatively affect the industry, he said.

About 45% of all pharmacies were in rural areas. By using managed-health-care principles in accessible community pharmacies, the pharmacy clinic had the potential to change the way health care was delivered, he said.

Clinics inside pharmacies would be staffed by a primary-health care nurse, supported by a general practitioner. Service patients would pay R30 for a PHC nurse consultation and diagnosis and the necessary treatment, dispensed by the pharmacist.

Patients would be recruited through employer groups and pay monthly fees of between R104 and R120 per member for nurse and general-practitioner consultations and treatment.

Body is bitter about pills

(96)

Health Department strikes back at criticism of its plans to cut back on doctors dispensing drugs instead of pharmacies

Star 12/8/96

Medical Correspondent

The Health Department has hit back at criticism of its moves to clamp down on dispensing doctors by detailing the alarming problems endemic in the sector.

New regulations for dispensing doctors were gazetted for comment on July 12.

Medical practitioners have accused the department of robbing them of their right to dispense and preventing about 3 million patients from getting one-stop services.

Problems with dispensing doctors were uncovered during Medicines Control Council inspections, and were one of the reasons why the National Drug Policy (NDP) was formulated, the department said in a statement.

More than 60% of practices did not have suitable medicine containers, which meant medicines could be adversely affected by humidity and light.

More than half the practices inspected allowed dispensing by untrained people, in some cases even the receptionist.

Other problems were:

- Inadequate storage and dispensing facilities. In 39% of practices, medicines which were supposed to be stored under cool conditions were not, running the risk of their being rendered ineffective or dangerous.
- Medicines were stored in unhygienic conditions.
- In a third of practices, capsules and tablets were hand-counted, and therefore possibly contaminated.
- Paediatric antibiotics were sometimes dispensed in powder form, rather than being correctly reconstituted before being dispensed, which meant children could be given the wrong concentration of a drug.
- Almost a third of practices had no suitable labels: patients were given inadequate information on how to take the medicines and there were no expiry dates, or batch numbers on the labels.

The department said it recognised the vital service dispensing doctors played in townships and rural areas, and intended to regulate, not disrupt, these services.

The NDP meant that only registered practitioners, whose premises had been registered and licensed, would be allowed to dispense, and only where there were no separate pharmaceutical services.

Bada Pharasi, chief director, registration, regulation and procurement, said the department believed its regulations were "well considered", but was prepared to debate factual comment.

"The doctors' views are inconsistent and confusing, they've made a 360-degree shift in attitude over the past year, and their contribution to last week's meeting was disappointing," he said.

Doctors' claims to a right to dispense was not valid, he added.

"The most qualified professional must do the task. We move from the premise that medicines and health care are not ordinary commodities of trade," Pharasi said.

An alliance of groups representing some 18 000 practitioners was to meet in Port Elizabeth at the weekend to prepare a response to the regulations.

Shock for doctors who sell medicine

(96)

ST 18/8/96

By CAS St LEGER

DOCTORS fighting to keep their right to sell pharmaceutical drugs will soon be confronted with damning evidence of incompetence.

Bader Pharasi, the health department's chief director of registration, regulation and procurement, is steering draft proposals towards withdrawing doctors' dispensing rights.

The issue is to be discussed at a meeting of medical organisations held in Johannesburg today.

This week, Pharasi and the department's chief pharmacist, Marius Fourie, showed the Sunday Times photos taken of 1 103 of the country's 8 000 licensed dispensing doctors.

One depicts a cockroach-catching device on a shelf conveniently placed surrounded by drugs. Another depicts a grubby plastic bucket, jam-packed with disposable syringes being "washed" before re-use.

Others show syringes pre-filled with penicillin and, claims Fourie, left unrefrigerated for a fortnight. The contents of one of them are semi-solid.

"And here is a patients' toilet leading off a dispensary," says Fourie, passing over a picture of a filthy, brown-encrusted lavatory.

"What doctor with a toilet like that should be driving one of these," he asks, turning up a picture of a gleaming white BMW.

Over half the doctors who were inspected failed as safe and hygienic dispensers of drugs. Only 16 percent had refrigerators.

There is also more run-of-the-mill ammunition — medicine bottles and packets identified by nothing but the price; 40 percent of drugs not properly labelled with names and instructions; more than half the drugs dispensed not by the doctor but often by illiterate people; and buy-one, get-one-free invoices from drug companies.

Pharasi, who has a pharmaceutical background, has been working on the proposed legislation since 1994.

It calls for doctors to be prevented from selling drugs to their patients if there is a pharmacy nearby, and for all doctors who are allowed to dispense — for example, in country areas where there is nowhere else to buy medicines — to be licensed and in possession of a certificate of competence.

"The last thing we want to do is remove vital services," says Pharasi.

"This would not be a total ban on dispensing but neither would there be an automatic licence for rural doctors."

He says patient safety and drug prices are the main motivations for new controls.

Surveys have shown that a dispensing doctor gives his patients an average of 2,38 items, compared with 1,67 items for a doctor writing out prescriptions for a pharmacist to fill.

Dispensing doctors account for 74 percent of total medical aid drug costs.

"One medical aid is investigating a case where a dispensing doctor in Kwazulu Natal is claiming up to R20 000 a day for medicine," Pharasi says.

But Dr Norman Mabasa, deputy chairman of the South African Medical and Dental Practitioners, dismisses the criticism.

"It's just a matter of training. The problems can all be solved easily with training.

"As for the gripe on costs, we dispense drugs out of necessity. We have offered to agree the profit motive be removed," he says.

"We're prepared to dispense for a handling fee only. We will jealously protect the rights of doctors to dispense."

Doctors fight back on medicine curbs

(93)(96)

By Melanie-Ann Feris

The medical fraternity is seeking a meeting with the Government to discuss proposals to replace the gazetted regulations on the dispensing of medicine by doctors.

The fraternity believes it is united on the issue of doctors being allowed to continue dispensing medicine.

At a meeting in Johannesburg yesterday, medical associations such as the Medical Association of South Africa, the Family Practitioners Association and the Eastern Cape Medical Guild said doctors were adequately trained to dispense medicine.

New regulations gazetted on July 12 has come under sharp criticism by doctors, who have accused the Department of Health of preventing about 3 million patients from getting one-stop services.

Star 19/8/96

Doctors to challenge ban on dispensing

Sowetan 19/8/96

By Khangale Makhado

ORGANISATIONS in the medical profession are to seek an urgent meeting with the Government in a bid to stop legislation that will bar doctors from dispensing medicine.

The decision was taken after a meeting at Johannesburg International Airport yesterday attended by the leadership of eight national organisations including the Medical Association of South Africa (MASA), National Convention on Dispensing, Family Practitioners Associations and the South African Medical and Dental Practitioners.

The Government recently put forward proposals which, if enacted, will affect over 6 000 doctors in private practices countrywide.

Availability of medication

Speaking on behalf of the newly formed forum, Masa executive member Dr Ivan McCusker said they had achieved unity in the profession and all agreed that doctors were adequately trained to dispense medicine to patients.

Dispensing by doctors, he said, was of value to patients in terms of access and the availability of medication and the present proposals may deny patients the right to proper health care.

"The forum shares with government a commitment and care for the welfare of our patients in both the public and private sectors.

"We feel optimistic that consensus will be reached with the government for both the benefit of patients and practitioners," said McCusker.

Forum chairman Dr Sam Motumi said the majority of dispensing doctors who belong to individual organisations that were present at the meeting yesterday supported the idea of dispensing medicine.

He said the only time doctors would consider legal action against the proposed legislation would be when the Government shows unwillingness to amend it.

Dispensing doctors' dilemma

(96) ARG 21/8/96

THE Department of Health has proposed new regulations for doctors who dispense medicines, a move which doctors strongly oppose because they say the regulations are a threat to the much-needed service they provide. Should doctors be allowed to dispense medicines, and what is behind the move to control them? Health Reporter **JENNY VIALL** investigates.

DOCTORS who dispense medicines fear that the Department of Health's proposed regulations will deny millions of patients access to health care, and result in bankruptcy for many doctors.

The regulations, which affect the 6 000 registered dispensing doctors in South Africa, require doctors to be licensed every year and to pass examinations on dispensing.

They stipulate that doctors will be allowed to dispense medicines only if separate pharmaceutical services are not available, although the distance of the service from a doctor has not been specified. The regulations also require more stringent control over storage and labelling of medicines.

Dispensing doctors have responded to the regulations by forming a coalition called the National Convention on Dispensing, to protect their rights.

The new regulations, they say, are punitive and counterproductive. Bada Pharasi, director in the Department of Health responsible for regulations, said the move to control dispensing doctors was in the best interests of patients.

He said one of the aims of the National Drug Policy was to give every South African access to affordable essential medicines, and the regulations were one of the ways to ensure this happened.

"We are opposed to people who profiteer from the provision of health care. Medicines are not an ordinary commodity, and not subject to free market trade," he said.

"We are not proposing an outright ban on dispensing doctors. There will be exceptional circumstances and we must make allowances for rural communities and townships."

Mr Pharasi said some of the problems experienced with dis-

of service, lack of training in dispensing, and a practice known as bonusing whereby pharmaceutical companies give doctors holidays or television sets as "bonuses" for stocking their products.

"We worry that this interferes with clinical judgment," said Mr Pharasi. "The patient is not in the best position to know this fact (about bonuses) or to know what is the best drug for an ailment."

Theodore Rai, executive member of the Dispensing Family Practitioners' Association, said he believed the effect of the regulations would be to stop most doctors from dispensing medicines, putting an end to the comprehensive, accessible and cheap service they provided.

"The regulations have nothing to do with stopping doctors from profiteering from medicines, but rather serve to deny doctors the right to dispense medicines and make pharmacies the preferred providers," said Dr Rai.

He said more than half the patients seeing dispensing doctors had insufficient money to pay: "In many cases we give patients medicines for free." While doctors oppose the regulations, pharmacists support them because they say doctors are not qualified to dispense medicines.

Ivan Kotze, director of the Pharmaceutical Society of South Africa, said the pharmacist's role was to act as a check on the doctor: "The focus of the doctor is the patient, the focus of the pharmacist is the product and whether it is correct for a particular patient.

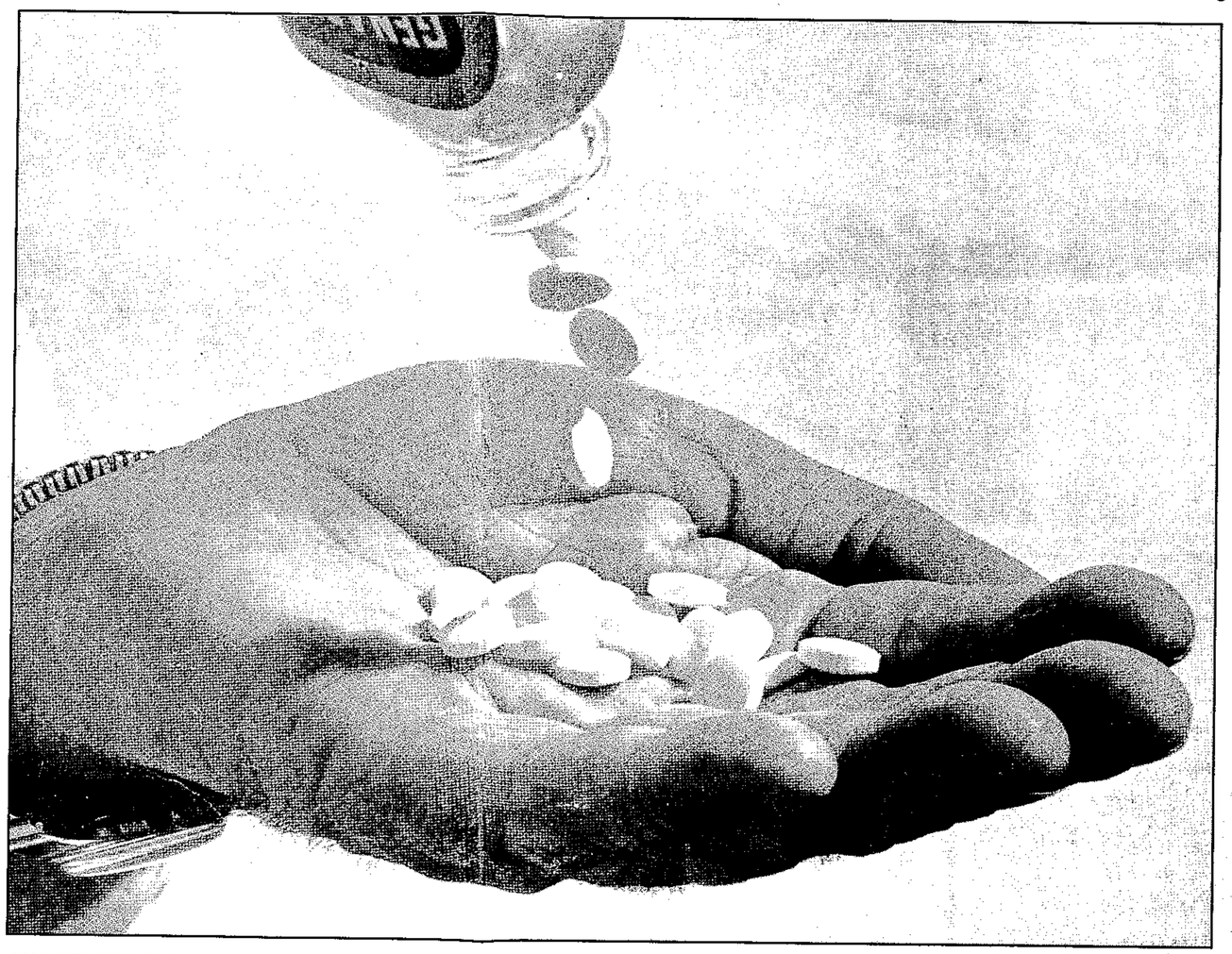
A pharmacist is essential to evaluate the prescription. If there is a problem with the medicine, there can be litigation against a pharmacist. If something goes wrong when a doctor prescribes, he's not going to tell anyone."

Dr Rai said doctors had been dispensing for a long time and

QUOTE

What is the difference between giving a person a penicillin injection and taking pills off the shelf?

Theodore Rai
Dispensing Family Practitioners' Association



SHAKE 'EM OUT: It's as easy as taking a pill bottle off the shelf and shaking out a few pills for a patient. . .or is it?

the difference between giving a person a penicillin injection and taking pills off the shelf? Our medical qualifications give us every right to do that.

"We know about drug interactions, and the idea that pharmacists exclusively should do this is fallacious. In the past pharmacists made up medicines, but no longer. The pharmaceutical companies do that now.

"The Department of Health is giving nurse practitioners working at clinics the right to dispense medicines. If it is safe and

how dare they say doctors can't?"

Steve Jooste, of the Cape Independent Practitioners' Association, said medicine costs would not be reduced by cutting out the dispensing doctor.

"This is like shooting the messenger because you don't like the message. Medicine use must be controlled and rational prescribing encouraged," he said.

"A comprehensive joint government-private sector strategy is needed to bring medicine prices down, not a series of impractical unilaterally imposed regula-

Doctors are also angry that the criteria for awarding licences have not been set out.

Ivan McKusker of the Medical Association of South Africa (Masa) said there was concern that the proposed legislation would allow the minister or director-general of health to change the conditions under which dispensing was allowed simply by promulgating regulations without consultation.

He said the proposed regulations would restrict access to health care and contradict the

quality health care more accessible.

Doctors would find it almost impossible to continue providing one-stop comprehensive services.

"Thousands of patients who depend on these services will be forced to get their medicines elsewhere, which will be extremely inconvenient and for many patients practically impossible," sid Mr McKusker.

"Our major concern is that the right of doctors to dispense will be removed or made difficult. It

Regulations aren't fair – claim

Health Reporter

REGULATIONS on the storage and dispensing of medicines are discriminatory as they apply only to doctors and not to state facilities, say doctors.

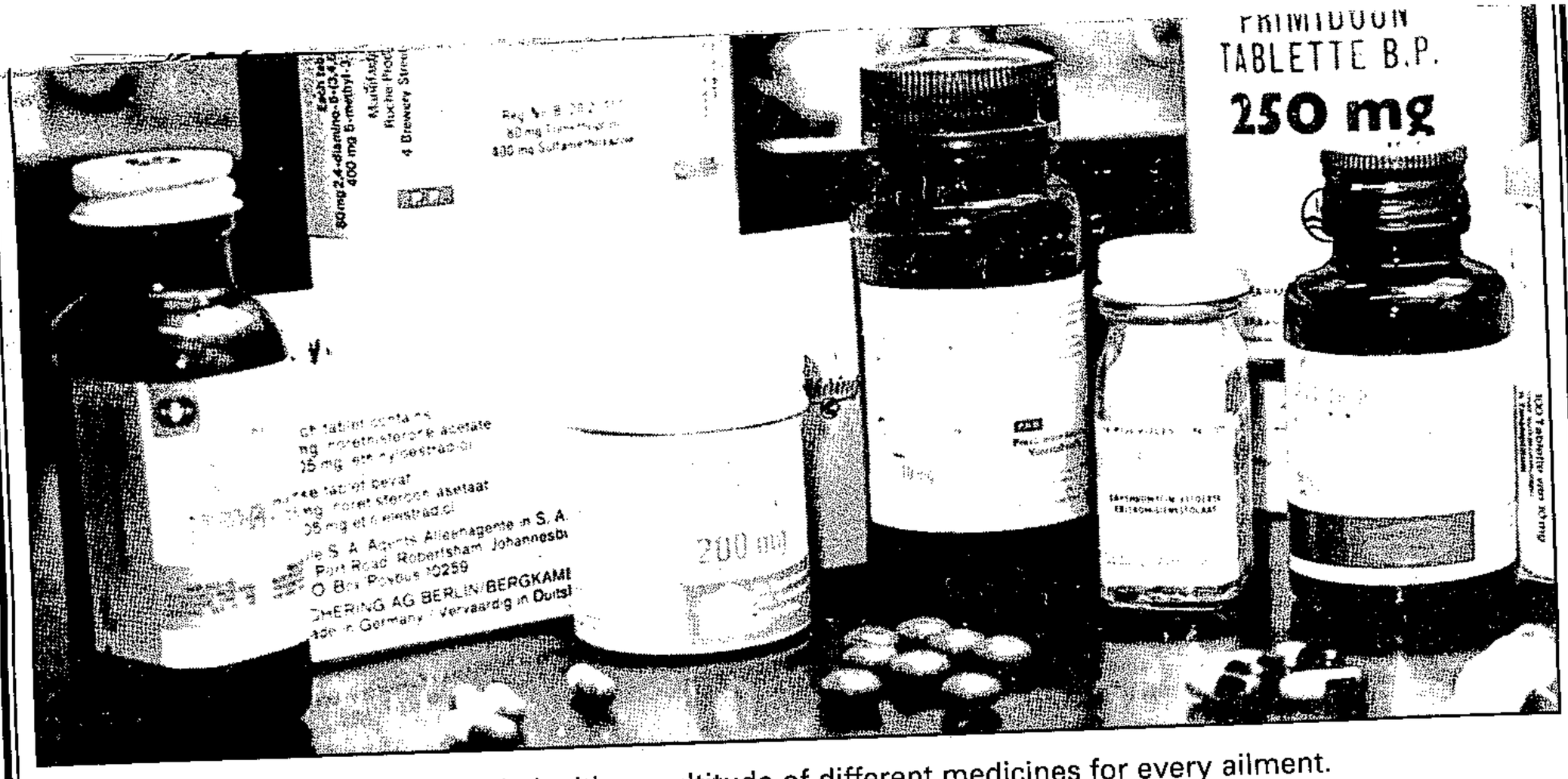
Although doctors support the move to improve quality control through patient information leaflets and childproof containers, they say the public health sector is also guilty of transgressions.

The proposed regulations on packaging are aimed at dispensing violations and controlling the safety and quality of medicines at dispensing sites.

A study by the Medicines Control Council on dispensing doctors found problems with storage, packaging, expiry dates, the handling of medicines and their labelling.

Patients were not told what the medicine was supposed to do, side-effects or how it should be taken (with food, how frequently), nor what food to avoid while taking the medicine. Some of the problems identified in the study were:

- **Inadequate facilities for storage and dispensing medicine, and in some cases medicines that should have been in cold storage were not. This can lead to medicines becoming ineffective or dangerous.**
- **In 52 percent of practices, medicines were dispensed by people not properly trained to do so, like receptionists.**
- **Medicines were stored in unhygienic conditions and not clearly labelled in 21 percent of inspected premises.**
- **In 33 percent of practices, tablets and capsules were counted by hand, which could lead to contamination of medicines.**
- **In 61 percent of cases there were no suitable containers for dispensing medicines adversely affected by humidity and light.**
- **In some cases patients were given antibiotic powder only and were expected to add water at home with no proper measuring devices to ensure precise volume. This could lead to wrong concentrations of antibiotic being given to children.**
- **In 27 percent of cases there were no suitable labels on medicines, inadequate information on how to use them, no expiry dates, no batch numbers to facilitate recall**



PILL BOXES: The market is flooded with a multitude of different medicines for every ailment.

'Hard-pressed state clinics could not cope with rise in demand'

ARG 21/8/96 (96)

Health Reporter

SOUTH Africa has one of the highest number of dispensing doctors in the world, a situation which has come about because of need, especially in rural and low-income areas.

During the apartheid years, half the health budget was spent on 20 percent of the population, which led to doctors performing many functions under one roof, said Theodore Rai, executive member of the Dispensing Family Practitioners' Association.

By dispensing medicines, doctors could offer a comprehensive, affordable and accessible service. But dispensing had also subsidised doctors' consultation fees, which some believed were too low.

Dr Rai said dispensing doctors could offer an all-inclusive service of R40 to R60 a person. "That includes medicines, consultation, procedures, dressings and sutures. Compare that to the average price of a script at a chemist which is from R100 to R150."

The regulations, doctors believe, will mean that many marginal practices will not be financially viable.

"I'd probably have to close down," said one doctor.

This, said Dr Rai, would mean that millions of patients would be forced to use the already hard-pressed state health system. "Day hospitals can already not cope," he said.

"Government has a stated policy of free health care for all. But we know that the demand for services exceeds the supply. In the interim phase while clinics are being built, this is not going to change.

"If the effect of the regulations, which we believe it will be, is that the majority of doctors are denied licences, we estimate that three million patients will be queueing for medicines at clinics that are already stretched."

One of the arguments against dispensing is that doctors may overprescribe medicines to make more money.

A study by the Representative Association of Medical Societies (Rams) found that when doctors dispensed, the average number of items given to patients was 3,8 as opposed to 2,8 dispensed by pharmacies.

On the other hand, doctors who get good deals from pharmaceutical companies say they pass savings on to their patients. Figures from Sanmed, a medical aid, show that prescriptions (processed from January to May this year) cost an average of R120,25 from doctors and R146,42 from pharmacies.

"But," cautions Martin de Villiers, medical director of Networks at Sanlam Health Care, "these figures are difficult to interpret as we don't know the number of items per prescription. What we can say is that if dispensing doctors' medicines were all pharmacy dispensed, it would cost R9,5 million more."

However, these figures do not take into account non-medical aid patients, and they are the ones who benefit from the low-cost service provided by many dispensing doctors.

Dr De Villiers believes dispensing doctors are definitely needed, especially for uninsured patients.

While doctors acknowledge that there are abuses in dispensing, they believe there are mechanisms in place to deal with them.

Sufficient regulations existed to police doctors, and it was up to patients and medical aids to utilise channels, said Dr De Villiers.

With managed health care systems being set up, medicine costs could be controlled through accurately measuring doctors' dispensing and prescribing.

Dr Rai said doctors violating ethical codes by overprescribing should be taken to task.

"But they are in the minority. If necessary, the South African Medical and Dental Council can be beefed up."

A powerful mechanism to control medicine prices would be the introduction of one exit price on medicines. This was proposed by the National Drug Policy, and would mean that doctors, pharmacies and the state buy medicine at the same price.

Medicine providers are then paid a fee to dispense, removing the incentive to give more expensive drugs and over-prescribe.

But, said Dr De Villiers, profits went to pharmaceutical companies, whose markup was from 600 to 2 000 percent.

MOTORSPORT

Doctors on warpath over drugs plan

ST(CM) 25/8/96

By PREGA GOVENDER

EMBATTLED doctors are urging patients to sign a nationwide petition calling on the government to scrap plans to prevent doctors dispensing pharmaceutical drugs.

Doctors, confident of getting over three million signatures by the end of September, have threatened to intensify their mass action campaign if the Department of Health goes ahead with its proposal to withdraw the dispensing rights of doctors.

In a move aimed at protecting the rights of doctors, an organisation known as the Affordable Medicine Trust has been formed for the purpose of taking legal action to defend the rights of medical practitioners and dentists.

Dr Bharuth Seetharam, an executive member of the Family Practitioners' Association, said doctors throughout the country had been asked to pay a fee of R500 into the trust in a bid to defend their basic rights.

Doctors are opposed to the proposed amendments of the Medicine and Related Substances Act of 1965 published in the Government Gazette last month which will prevent them from dispensing medicines.

"We are angry that the Department of Health did not consult with representatives of the medical profession when the proposal was first mooted.

"They also completely bypassed the South African Medical and Dental Council.

"If doctors are barred from dispensing medicines, the cost of health care will skyrocket.

"In addition to a consultation fee paid to a doctor, the patient will now also have to pay the pharmacist a dispensing fee, as well as pay for the medicines.

"What will happen if a pharmacist refuses to give a patient medicine on account?

"The danger of allowing only pharmacists to prescribe medicine is that a monopoly will be created, making them the sole distributors," he said.

Seetharam, a ministerial appointee on the interim SA Pharmacy Council, said that input from doctors on the dispensing issue would be handed to the department.

"If our input is not received favourably we will muster support from our patients and hold marches and demonstrations."

He lashed out at politicians for meddling in the professional activity of doctors.

Dr Lalitha Badul of Estcourt, who is spearheading the campaign in the Natal Midlands, said the proposals allowed for patients in rural areas, where no pharmaceutical services were available, to receive medicine from doctors.

But doctors would have to apply for a licence from the Registrar of Medicine.

"And the licence is not automatic," said Badul.

Back to the drawing board: Doctors will need additional training before they are allowed to dispense drugs

Doctors say new rules are a sick idea

M+G 23-29/8/96

(96)

Proposals by the Department of Health to curb the dispensing of medicines by doctors will create all kinds of other problems, reports **Rehana Rossouw**

SOME three million patients across South Africa receive medication from their doctors every month. By the end of September, the Department of Health will have changed this.

Dispensing doctors have united to slam proposals by the department to curb their right to dispense medicines. They say it will drive up the cost of health care for the poorest sector of society.

The National Convention of Dispensing Doctors (NCDD), which represents 7 200 of South Africa's 8 000 dispensing doctors, says most of their patients live in disadvantaged areas where there are no pharmacies or where facilities close after working hours.

"Our typical patient cannot afford to take time off work to see the doctor, so he visits the surgery after working hours, long after the day hospitals accept their last patients for treatment," said NCDD representative Dr Theodore Rai.

"By the time he leaves the surgery, if there is a pharmacy in the area, which is often unlikely, it will be closed. It is too dangerous for him to take public transport to another area to find a pharmacy, so he relies on his GP to dispense medicine.

"What the department is doing is removing the GP's tools to treat the patients. Many people who see doctors in disadvantaged areas don't just want to hear that they have gastroenteritis or bronchitis, they expect the doctor to help them cure it as well."

Not true, said the department's chief director of registration, regulation and procurement, Bader Pharasi, who is steering the draft regulations to withdraw doctors' rights to dispense medicines. The department wanted to ensure patients receive medication from the people best trained to do so — practising pharmacists.

Pharasi said the department had found shocking examples of unsafe and unhygienic premises in visits to 1 103 dispensing doctors. Medicines were not properly labelled with names and usage instructions; syringes were re-used, premises were dirty and medicines were stored at room temperature instead of in refrigerators.

He said the amendments to the Medicines Control Act, which will require doctors to receive additional training and certification before they are allowed to dispense, was aimed at providing patients with the best service. Doctors were not trained in pharmacology, and dispensing doctors' premises were not inspected regularly.

"Traditionally, throughout the world, diagnostic and dispensing services are separated. The department has been investigating this issue since 1994 and we are not advocating a total ban on dispensing doctors, we just want to ensure they are properly trained to do the job properly."

He admitted pharmacies were not widely available in disadvantaged areas, and said the department would examine introducing regulations to make it incumbent on existing pharmacies to open after hours.

'The department claims to have shocking evidence about bad practices, but it has not referred the doctors for disciplinary action'

Rai said he doubted the department's "survey" of 1 103 dispensing doctors had been scientific. There were existing channels to censure dispensing doctors who practised in unhygienic conditions or prescribed the wrong medication. The Interim Medical and Dental Council could take action against these doctors.

"I find it strange that the department is sitting on these examples of bad practices among dispensing doctors and using them as a tool to justify their actions. It claims to have shocking evidence, but it has not referred these doctors to the council for disciplinary action. It is completely derelict in its duty to the public."

Doctors and other interested parties have been given until the end of August to comment on the proposals. The NCDD has sent a memorandum to the department objecting to the proposals and has asked patients to write to Minister of Health Nkosazana Zuma, expressing their opposition.

They are also concerned that the changes will push up the prices of medication. "We see indigent patients who pay between R30 and R60 for consultations and get their medication free. This makes up about 30% of our members' patients," said Rai. "These people will have to go to state hospitals — we estimate they would total about 600 000 patients each month. State facilities are already overburdened, and it is unlikely that these people would receive better care than we provide.

'We also have contractual agreements with trade union sick funds to provide their members' medicines at cost price. I doubt whether pharmacies will provide medicines at cost. The only patients from whom we make a profit are those who belong to medical aid schemes, and believe me, those bills are scrutinised, so there is little chance of profiteering."

Pharasi said doctors who provided medication for sick fund members would be "treated on their own merits". If it was in the patients' interest for them to continue dispensing, the department would have to ensure those doctors were competent to do so.

The NCDD is outraged by the department's failure to consult it before publishing the amendments in the *Government Gazette* in April.

"The department only met us in April, after we requested a meeting and paid for a venue. We asked for a follow-up meeting to present our case, and were allowed one delegate in a meeting of 30 people," said Rai.

Pharasi admitted the department had only consulted two organisations, representing dispensing doctors in Gauteng and KwaZulu-Natal, before publishing the regulations. But the department held workshops on the issue last year and had used the media to publicise its new policy.

Drug industry slams Zuma's anti-theft plan

(96) ST 1/9/96

By CRAIG DOONAN

THE Minister of Health, Dr Nkosazana Zuma, has been caught up in another row — this time over plans to "ram" through an anti-drug theft system which could cost the pharmaceutical industry about R1-billion and cause the price of medicine to rocket.

And the top drug-squad policeman punting the system has a son working for a company linked to the new plan.

Leading players in the drug industry sent an urgent submission to Zuma this week, calling on her to scrap her proposed "non-validated, non-tried, cost-driving plan . . . which promises very definite and indeterminate cost escalations".

If the plan is adopted, manufacturers will have to mark all drug packaging with a digital stamp which will act as an identity tag. The identities will be stored in a computer system managed by the Department of Health.

All drugs would thus be traceable. The ministry hopes this will stop medicine theft, which costs more than R1-billion a year.

Captain Daan Davis, the national co-ordinator for pharmaceutical investigations, is punting a tracking system called Vericode. His son Willem works at Verimed, the company that presented Vericode to Zuma.

Davis said this week he had suggested only that a system such as Vericode be considered: "We never said go for Vericode. It's just an example of what we can do. We said to the industry: 'If you can come with something better, let's take it'."

He said that although his son worked for the company, his job had nothing to do with the tracking system.

But the drug-manufacturing industry says the system has never been tested in a pharmaceutical environment, will cost millions to introduce, will push up the price of medicine, and is being hurried through.

Paul Glover, a member of the Pharmaceutical Manufacturers Association's science and technology committee, said Zuma's plan would be a "nightmare" to implement.

"The state is asking the industry to finance the solution to theft for them. We're telling them it's not going to work. It's impractical and cannot be implemented," he said.

The manufacturers' submission this week said the special mark alone could cost the industry R500-million a year — "a disproportionately high cost given that the total annual worth of the industry does not exceed R7-billion".

"If one takes other elements into consideration, such as the modifications required for packaging equipment, investment in scanners, computer hardware and software, the total bill could easily reach R1-billion in the first year of implementation," Glover said.

"The man in the street will eventually have to pay for it."

The Registrar of Medicines in the Department of Health, Professor Johann Schlebusch, who has been working on the new system, said that while there might be start-up costs, "these should perhaps be balanced against the losses taking place".

He said: "When stolen medicines are rechannelled into illicit routes, they are competition for pharmaceutical agencies; so what one loses on the corners, one may be making up on the straights.

"There is a huge theft problem. When medicines are diverted to illicit channels you don't know how they are stored, how they are transported, at what temperature they're being kept or whether safety is being compromised.

"At the end of the process, the public may be taking ineffective medicine so there's a real obligation on the powers that be to bring the system under control."

Barney Sachs, the executive director of the National Association of Pharmaceutical Manufacturers, said about 80 percent of thefts took place at state hospitals and warehouses, and "they have to tighten up their own control".

Doctors see light in TB battle

(91) BD 5/9/96

DURBAN — A team of KwaZulu-Natal researchers yesterday said an ultraviolet lamp might hold the key to preventing the spread of tuberculosis and other air-transmitted diseases.

Addressing a media briefing in Durban on their research findings, they said the experimental breakthrough represented two world firsts.

These were the successful use of germicidal ultraviolet light in endemic conditions and air samplers to culture atmospheric tuberculosis bacteria.

"The experiment is the first in the world to have the ability to capture and identify TB bacteria in the air," said researcher Vinodh Gathiram.

Gathiram said health workers would be less exposed to TB, declared by the World Health Organisation to be humanity's greatest killer. Patient cross infectionwould also be reduced.

The research was carried out over one year on 118 TB patients at King George V Hospital in Durban.

Germicidal ultraviolet lamps were placed 6cm below the ceiling in the four wards and were timed to capture all the bacterial air.

"We have managed to capture and grow the TB organism from the air in four hospital wards, which to the best of our knowledge has never been done before," said Philip Onyebujoh, a senior specialist seconded to the SA Medical Council's TB programme.

"By reducing the bacterial loading in the air in hospital wards, the spread of TB by droplet infection can be considerably reduced."

KwaZulu-Natal health MEC Zweli Mkhize said the research had put the province on the global health map.

He said the new technology would, if proved to be applicable, be used in hospitals to help the fight against curable diseases such as TB and flu.

The research team will present a paper on its findings to an international medical journal and the experiment is expected to go into a second phase of testing for a year. — Sapa.

NEWS

Dispensing plan 'to hit poor hardest'

Cape Flats doctors protest against medicine proposal

(96) ARG 17/9/96

JENNY VIALL AND JUDY DAMON
HEALTH REPORTERS

Government moves to stop doctors from dispensing medicines may be a way to force general practitioners into the public sector.

This was one of the views put to the National Assembly portfolio committee on health which heard 38 submissions yesterday from dispensing doctors, community organisations and pharmacists on proposed regulations to control dispensing doctors. Dispensing doctors, most from the Cape Flats, marched to Parliament yesterday to protest against the plan.

The doctors claimed patients from disadvantaged communities would suffer and that for some it could be a fine line "between life and death".

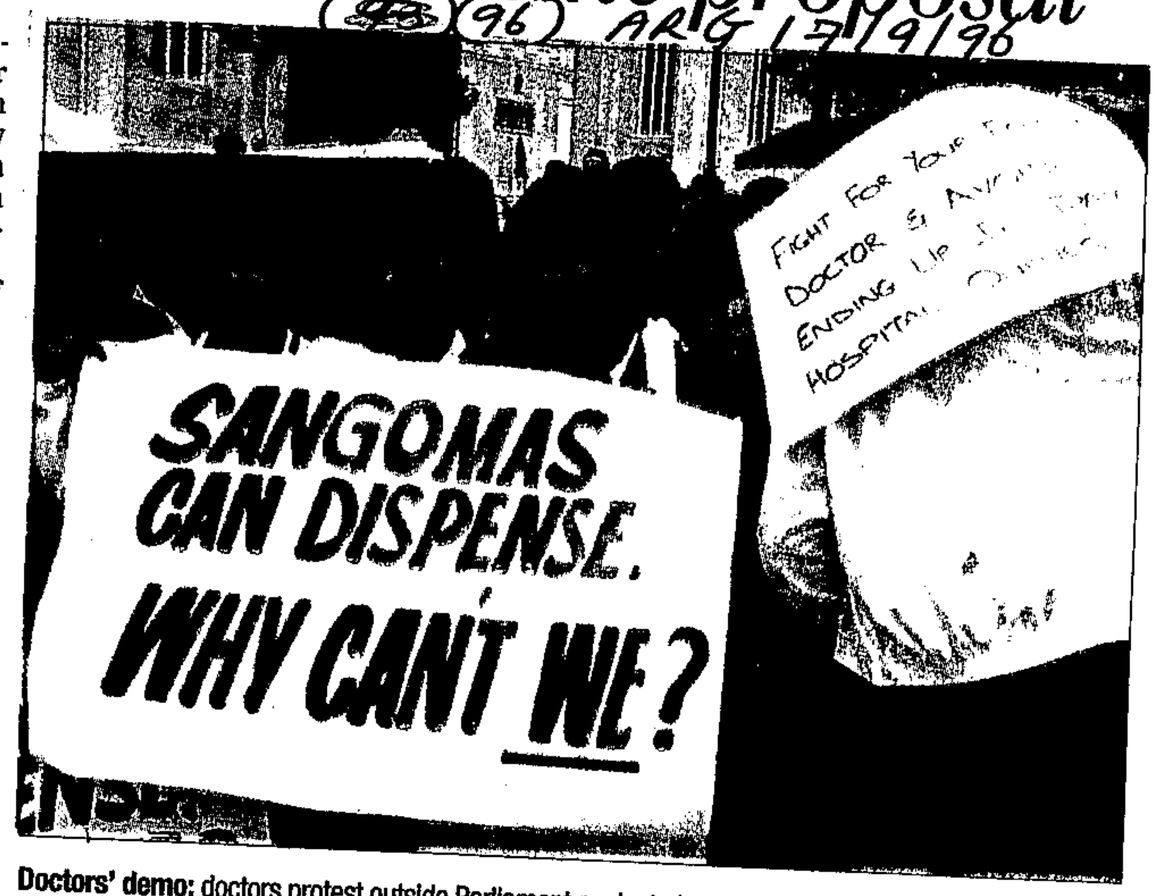
Jackie Pepler, a doctor from the National General Practitioners Group, said that apart from forcing doctors out of business, regulations on dispensing would also force many patients to seek their medication from the already overburdened public health system.

The proposed regulations have been greeted with outrage by dispensing doctors and community organisations. If implemented, many dispensing doctors will have their licences revoked. Doctors will also have to register to dispense drugs annually and do a course in dispensing.

Many people opposed to the regulations told the committee that those hardest hit would be the poorer patients who could not afford medicines from pharmacists or could not easily get transport to pharmacies. Elaine Clarke of the Dispensing Family Practitioners Association questioned whether the health system would cope with the extra three million patients who would use clinics if dispensing doctors were no longer able to dispense. "We call on the department to withdraw the regulations and give us an undertaking that no legislation be introduced without consultation," she said.

Bada Pharasi, director of health services, told the committee public safety was the main aim of the regulations, which would bring South Africa in line with international principles that separate dispensing functions from diagnosing and prescribing.

Judi Fortuin of the Progressive Primary Health Care Network told the committee the regulations raised more issues than they addressed. One was the legality of the regulation, which in effect superseded an act of Parliament. Ms Fortuin questioned the inalienable right of doctors to dispense medicines.



Doctors' demo: doctors protest outside Parliament against plans to stop them dispensing medicines

Doctors, pharmacists square up

POLITICAL STAFF (96)

CT 17/9/96

DISPENSING doctors and pharmacists squared up to each other yesterday at public hearings in Parliament on Health Minister Dr Nkosazana Zuma's regulations aimed at curbing the right of doctors to dispense drugs.

The proposals include measures to stop doctors from dispensing drugs and the substitution of trademark drugs with generic products.

The Department of Health said visits to dispensing doctors' rooms showed their premises to be unsafe and unhygienic, a claim that was contested by the doctors.

The Gauteng Pharmacists' Forum said it, together with the Pharmaceutical Society of South Africa and other bodies, had "shown that the perverse incentives offered by profit on medicines, discriminatory pricing policies by manufacturers, free trips, and other irregularities had created not only unfair practices but also practices which mitigate against the patient being given the best medicine for the illness at a price which the patient can afford".

The forum said black pharmacists in the townships had little chance of establishing a full service while doctors dispensed medicines.

Doctors were known to be making profits of up to 900% on the sale of drugs, the forum claimed.

It also claimed that dispensing doctors tended to prescribe more drugs, evaded paying VAT and traded in stolen medicines.

"Dispensing doctors have a captive market ... a limited inventory specially tuned to the greatest profit margin rather than a comprehensive range of products," it said.

On behalf of the doctors, the Medical Association of South Africa argued that 83,88% of general practitioners and 26,78% of specialists offered dispensing facilities "as a convenient one-stop service".

"The proposed regulations interfere with freedom of choice in the doctor-patient relationship. It will restrict or remove doctors' rights to dispense medicines to their own patients and infringe on patients' rights to choose from whom to receive their medicines."

The prescriber was accountable for the patient's health and "must be able to specify the drug which according to his clinical judgment will provide the optimal effect".

MARCH ON PARLIAMENT

Medics protest over dispensing proposal

CT 17/9/96

WHILE THE PROPOSED LAW which would ban doctors from dispensing medicines was debated yesterday, a group of about 300 doctors and supporters marched on Parliament to protest against the planned changes.

DOCTORS marched on Parliament yesterday — but at Cape Flats clinics, it was just another day.

More people without appointments arrived at the Mitchells Plain Day Hospital yesterday, but hospitals on the Cape Flats were not affected by the doctors' march.

The 300-strong crowd of doctors, patients and staff members were protesting against a proposal to remove doctors' rights to dispense medicines which was being debated in Parliament yesterday.

The doctors, who last took to the streets three years ago to protest against VAT charges on medicine, handed over a memorandum for Health Minister Dr Nkosazana Zuma, asking that the proposal to remove doctors' rights to dispense medicines be withdrawn on the grounds that it did not serve public interest.

The regulation "would have severe implications for the delivery of medicines to three to five million people (a month) who are, because of economic circumstances, not able to buy medicines separately," the memorandum, which was signed by the chairman of the National Convention of Dispensing, Dr S Motumi, stated.

"By killing dispensing, the government is taking away a main source of income. It will make it difficult to remain in general practice, doctors will have to return to hospitals," a doctor said.

The Day Hospital in Mitchells Plain seemed to be the busiest out of the five day hospitals visited in the Cape Flats.

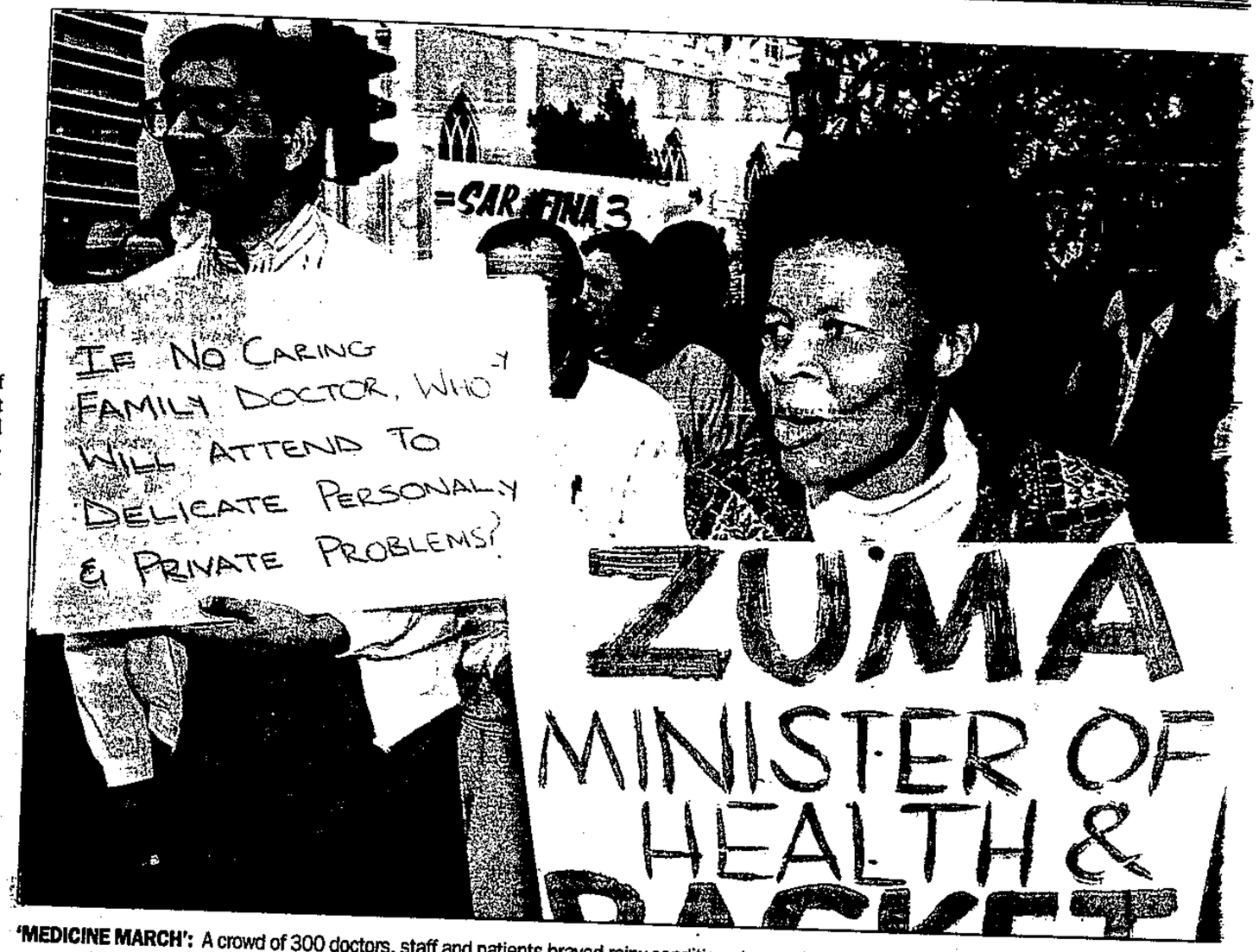
There was a larger volume of people without appointments at the Mitchells Plain Day Hospital yesterday which could be attributed to the doctors not being available for morning surgery.

The sister in charge could not say whether there were more patients, but she confirmed there were more walk-in patients.

The day hospitals in Hanover Park, Heideveld, Nyanga and Manenberg did not appear to be affected by the doctors' march.

● About 200 KwaZulu-Natal doctors marched to the provincial health department offices in Maritzburg yesterday to protest against the planned ban on doctors from dispensing medicine.

A group from Concerned Doctors for Dispensing handed a copy of their submission opposing the legislation to Dr Busi Nyembezi, who received it on behalf of the provincial health MEC. — Staff Writers, Sapa



'MEDICINE MARCH': A crowd of 300 doctors, staff and patients braved rainy conditions to march on Parliament yesterday to protest against a proposed law which would remove the right of doctors to dispense medicines.

PICTURE: ALAN TAYLOR

Pharmacists and doctors fight over health reforms

Star 17/9/96 (93)(96)

The new regulations – if passed – would stop doctors from dispensing medicines

By Patrick Bulger
Cape Town

Dispensing doctors and pharmacists squared up to each other yesterday at public hearings in Parliament on Dr Health Minister Nkosazana Zuma's regulations aimed at curbing the right of doctors to dispense drugs.

The regulations propose sweeping reforms to the dispensing system, including the substitution of trademark drugs with generic products in a bid to slash medicine costs. Included in the regulations is a measure to stop doctors dispensing drugs.

The Department of Health said numerous visits to doctors' rooms showed their premises to be unsafe and unhygienic, a claim contested by doctors.

According to Gauteng's Pharmacists' Forum, dispensing doctors demonstrate "a total disregard for the real concern about a patient's best interests".

"Together with the Pharmaceutical Society of SA and other bodies we have shown that the perverse incentives offered by profit on medicines, discriminatory pricing policies by manufacturers, free trips, television sets and other irregular practices have created not only unfair practices but practices which militate against the patient being given the best."

This was at a price which the patient could not afford and for a treatment period "which is optimal and not abusive", the forum said.

It said the "black entrepreneurial pharmacist" in townships had little chance of establishing a full service while doctors continued to dispense medicines. Doctors were known to be making profits of up to 900% on the sale of drugs, the forum claimed, and had a tendency to prescribe more drugs. It also said dispensing doctors evaded paying VAT and traded in stolen medicines.

> **They make up to 900% profit on drug sales**

However, the Medical Association of South Africa argued that 83,8% of general practitioners and 26,7% of specialists offered dispensing facilities "as a convenient one-stop service, during and after hours".

"Masa supports the Government in its efforts to make quality health care more affordable and accessible. The proposed regulations conflict with this objective and cannot be justified as in the public interest. In particular, they hold serious implications for the delivery of health care to poorer people," the association said.

"The proposed regulations interfere with freedom of choice in the doctor-patient relationship. It will restrict or remove doctors' rights to dispense medicines to their own patients and infringe patients' right to choose from whom to receive their medicines."

Backing for dispensing medics

Cape Town – The service provided by dispensing doctors saved non-medical aid patients an estimated R1,6-billion a year, National Medical and Dental Forum spokesman Dr Mohammed Adam said yesterday.

Addressing the National Assembly health committee hearings on proposed changes to regulations about pharmaceutical dispensing by doctors, Adam said restrictions on the rights of dispensing doctors would result in restrictions of access to health care and an increase in health costs.

This was not in the public interest and there were no sound reasons to limit dispensing by the medical profession, he said.

If the patients being seen by dispensing doctors were to get a prescription from pharmacists at an average rate of R50, it would cost the public an extra R1,6-billion a year.

The NMDF believed that existing laws and mechanisms should be used to ensure compliance with high standards of dispensing.

Restrictions on dispensing would penalise the very profession which served and continued to serve disadvantaged communities, Adam said. – Sapa.

Call for working group to discuss doctors' dispensing

CT 19/9/96 (96)

ANEEZ SALIE

THE National Assembly Portfolio Committee on Health is delighted at the success of two days of hearings this week into the controversial issues of medicine dispensing by doctors, and the lengthening of their training, says Dr Abe Nkomo, chairperson of the committee.

"It showed Parliament at its best," he said. "Difficult issues were tackled in a rational and considered manner and we hope we were able to point a way forward."

Yesterday Nkomo released preliminary details of the resolutions taken by the committee, ahead of a final report and recommendations.

On the proposed regulations to restrict doctors' right to dispense, the committee called for the urgent establishment of a working group, representative of public and private practitioners, pharmacists, the government and patients.

It should consider legal and technical aspects (with an emphasis on clarity and accuracy), as well as policy decisions in need of consensus, such as:

- Which bodies should regulate dispensing?
- Is the authority to dispense a necessary part of medical practise in South Africa?
- Is supplementary training for dispensing necessary? If so, how long, and administered by whom?
- Should the new regime apply to public and private sectors?
- How should inequalities be addressed?
- Is there a necessary conflict between doctors and pharmacists? If so, how can it be resolved?

On the Interim Medical and Dental Council's extended training proposals, the committee noted the importance of distinguishing between vocational training and community service, Nkomo said.

They required more research from the council to elaborate on the specific skill deficiencies of South African medical graduates, and on the amount of extra training time needed, as well as where such training was to take place and other logistical requirements.

Zuma's drug dispensing, community service proposals rejected

(96) (93) BD 20/9/96

Wyndham Hartley

CAPE TOWN — Parliament's ANC-dominated health committee has rejected Health Minister Nkosazana Zuma's suggestions that doctors should be stopped from dispensing drugs and that medical graduates should serve two years community service, and called for further investigations.

Zuma, besieged by Sarafina 2 allegations, has also been told that she had not consulted medical stakeholders sufficiently and the interim medical and dental council had been asked to do this.

ANC health committee chairman Abe Nkomo said the hearings this week had been a spectacular success, and called for a working group to be established to investigate the right of doctors to dispense medicines.

On the issue of a further two years service to the state by medical students, the health committee decided that there was a need for further research. Zuma and the health department proposed that medical graduates needed to serve a further two years of vocational training before they could be registered. This was characterised in evidence before the committee as "conscription" under the guise of further training.

Nkomo said that the interim medical and dental council had been asked to elaborate on details and the ramifications of the proposal, to consult fully with all stakeholders and report back to the committee.

Dispensing doctors backed by health body

(96)

CT 25/9/96

ANEEZ SALIE
HEALTH WRITER

THE 6 000 doctors battling to be allowed to continue dispensing medicine have received support from the influential National Progressive Primary Health Care Network.

The non-governmental umbrella body is concerned that Health Department plans to restrict and strictly control the dispensing of medicines by private doctors could be detrimental to communities.

It believes the most important consideration should be the right of all communities to receive accessible, affordable and safe healthcare services, which include medicines.

It has proposed that:

- The dispensing system needs rationalisation.
- Communities should be consulted about the changes.
- Patients must be given more information to allow them to make informed decisions about medicines.
- Medicines must be more and not less affordable.
- Medicines must remain accessible to communities.
- The dispensing of medicines must be safer under the new regulations.

NEWS

Drug companies seek deregulation of pharmacy ownership

(96) CT(BR) 26/9/96

SHIRLEY JONES

KWAZULU NATAL EDITOR

Durban — Pharmaceutical manufacturers are driving for the deregulation of pharmacy ownership in the wake of the health department's decision to withdraw doctors' dispensing rights.

Miryena Deeb, a spokesman for the Pharmaceutical Manufacturers' Association, said yesterday that the concentration of dispensing rights in the hands of community-owned pharmacies would reinforce an already disturbing retail cartel.

She said the pharmaceutical sector comprised a host of small businesses (2 500 countrywide) with small turnovers and high mark-ups. The retail pharmaceutical industry was grossly over traded, she said, pointing out that without dispensing doctors, the industry would be in a similar position to the early 1980s when there was little competition.

In terms of the Pharmacy Act, only qualified pharmacists may own pharmacies. Big business has lobbied for more than 20 years for a foothold in this R4 billion-a-year industry.

Deeb said though the association agreed that medicines should only be dispensed by qualified pharmacists, keeping retailers like Pick 'n Pay and Clicks out of the pharmaceutical retail sector, prevented them from using their bulk-buying power to secure better margins.

Deeb said that, as things stand, mark-ups on pharmaceuticals can be as high as 200 percent.

She said the 200 pharmaceutical manufacturers in South Africa gave large discounts to pharmacies which never reached the public.

Deeb said that if the health department introduced the writing of generic prescriptions, this would add to the myriad of abuses evident within the retail pharmaceutical industry.

Some pharmacists could be tempted to dispense the drug on which they were receiving the most favourable discount that week, rather than the most appropriate medication, she said.

Claude Ambler, the national president of the Association of Community Pharmacists, denied the existence of any retail cartel. "This is a free-market system. We are in direct competition with other pharmacies and people do shop around," he said.

Ambler said that up until 10 years ago, there had been a blue-book price for medicines. However, this no longer applied as fixing medicine prices had been outlawed by the Competition Board. That had stepped up competition.

Ambler said with the existing discount situation, profit on medicines was negligible and many pharmacies were struggling. He said that many of the pharmacies facing financial trouble had chosen to amalgamate rather than close down.

He said though pharmacies traditionally added a 50 percent mark-up on medicines, the discount provided to medical aids negated this. Prescriptions submitted to medical aids for payment necessitated discounts of at least 30 percent. Direct sales meant similar discounts.

Ambler questioned whether a drive to deregulate the industry was not profit seeking.

He said his association supported Nkosazana Zuma, the health minister, in her efforts to lower medicine prices and had urged its members to co-operate.

Ambler said Zuma's intention to force drug manufacturers to declare their selling prices would do away with discriminatory pricing, enabling customers to check prices against local and international benchmarks.

Health body's call 'not against Zuma'

BD 26/9/96 (96)

Wyndham Hartley

CAPE TOWN — The decision by Parliament's health committee to further investigate proposals to stop doctors dispensing medicines was not a repudiation of Health Minister Nkosazana Zuma, parliamentary sources said yesterday.

The decision showed the committee was doing its job and ensuring all organisations with an interest were consulted. They said the health department had not made a decision on dispensing doctors but had asked for submissions.

Committee chairman Abe Nkomo said his committee's decision was "not a setback for Zuma or for anybody else".

He said there was a lack of communication with many doctors and other parties who thought that Zuma and the health department had already made an announcement rather than asking for submissions. Some people thought it was already cast in stone and that was not the case, Nkomo said.

The Interim Medical and Dental Council's recommendations that medical graduates undergo a further two years "vocational training" had also been referred back to the council. Nkomo said medical schools had been consulted by the council but medical student organisations had apparently not been asked their opinion. Nkomo said there was a difference between vocational training and community service and further consultation would help iron out confusion.

Best-selling drug now sold without prescription

(96)

Star 26/9/96

Trend to over-the-counter sales has many benefits for consumer and medical profession, say marketers

The world's best-selling prescription drug, the antacid Zantac, is now available in a lower dosage from pharmacies, without a prescription from a doctor.

The drug was deregulated yesterday in the latest example of the pharmaceutical industry's shift from prescriptions to over-the-counter (OTC) sales.

Bill Collier, chief executive of manufacturers Glaxo-Wellcome, said descheduling was an international trend driven by the need for consumers to take control of their health and for governments to reduce health expenditure.

Latest figures reveal that Zantac, used largely to treat ulcers and stomach erosions, is a R17-billion-a-year market worldwide. Although available in 300mg and 150mg dosages at present, only the 75mg dosage will be available direct from pharmacies.

Collier said the OTC format gave individuals a wider choice of product, particularly in remote areas; freed doctors to concentrate on more serious diseases; and allowed pharmacists to use their professional skills to greater advantage.

It also allowed health insurance institutions and governments to make best use of limited resources, and manufacturers to make long-term plans, he said.

In the United Kingdom, according to the British Medical Journal, more drugs have changed from prescription to OTC status in the past two years than over the previous decade, and 65% of doctors say they feel comfortable with the OTC concept.

Policy for medicine licensing worldwide is for drugs to be made more easily available to patients unless a case can be made for restrictions.

The World Health Organisation supports self-medication as providing quick, effective relief for symptoms which don't need a medical consultation, Collier said.

To be descheduled, a product has to have a proven safety profile, and efficiency in self-limiting, easy-to-diagnose conditions, packaging and product information, and a pharmacist to supervise the sale. — Medical Correspondent.

SA may need to bend medical dispensing rules

(96) CT(BR) 30/9/96

JAMES LAMONT

INDUSTRIAL EDITOR

Johannesburg — South Africa had a strong case for allowing doctors to dispense medicine to patients even though dispensing and prescription by medical practitioners were normally separate concerns.

Donald de Korte, the chief executive of MSD, the pharmaceutical company, said last week it was healthy for the commercial sale of drugs not to be in the hands of prescribing doctors. But he warned that the rules should be flexible in South Africa where dispensing clinics might be the only source of medicine in isolated rural areas.

HERE TO STAY *Donald de Korte, the chief executive of MSD*

PHOTO: JOHN WOODROOF

Nkosazana Zuma, the health minister, has come under fire from the pharmaceutical industry for proposed controversial reforms to restrict the dispensing of medicine by doctors and make the prescribing of generic drugs mandatory. Zuma plans to allow only licensed persons to dispense medicine, which could rule out many doctors who distribute treatments from their surgeries.

The strained relations between the ministry and pharmaceutical firms came to a head earlier this month after President Nelson Mandela attacked the "monopolistic" hold of multinational pharmaceutical companies on the local market and implicated them in a conspiracy to topple Zuma.

Since then SmithKline Beecham has filed a submission to the Transvaal Supreme Court to overturn the proposed regulations, followed by allegations that international companies have been threatened with expulsion if legal action goes ahead. Boehringer Mannheim, the German pharmaceutical group, warned that foreign firms may pull out of South Africa if they are made to feel unwelcome.

De Korte said mandatory prescription of generic names for branded drugs could be "a violation of intellectual property rights", but said Zuma's goals of broadening access to medicine were those of the pharmaceutical industry. He insisted on a debate of the issues rather than confrontation, and said differences between the ministry and the drug industry had been blown out of proportion.

MSD is owned by Merck & Co, the US-based pharmaceutical company, which reinvested in South Africa by buying the local licensee, Logos Pharmaceuticals, from CG Smith. Logos had about $60 million sales a year and has operated as MSD since the beginning of September.

Merck pulled out of South Africa in 1978 for political reasons at a time when US pharmaceutical companies had 40 percent of the market share. Now they only have 15 percent.

"We have trust in the long-term future of South Africa," said De Korte. He said MSD was committed to supplying cost-effective treatment to the local market and was considering expanding its research capabilities in South Africa.

Govt plans to defend prescriptions policy

(96) BD 3/10/96

Jacqueline Zaina

GOVERNMENT planned to defend its policy in the legal fracas looming between the health department and pharmaceutical industry over pending legislation which drug manufacturers claim could prevent doctors from prescribing brand names.

Health department policy and planning deputy director-general Dr Ayanda Ntsaluba said government would defend its drug policy in court, if need be. It was seeking legal advice.

Pharmaceutical multinational SmithKline Beecham has started legal proceedings against Health Minister Nkosazana Zuma over her proposals to introduce the World Health Organisation's international non-proprietary names system of generic name prescribing.

Most major pharmaceutical firms — fearing it will be illegal to include the proprietary name on the prescription — are set to join the battle if Zuma refuses to withdraw regulations gazetted on July 12.

However, Ntsaluba said that as far as the content of the contested regulations was concerned, government remained immovable on its policy.

He said the regulations did not amount to a ban on prescribing of branded drugs, and they had been misinterpreted by drug manufacturers.

"The regulations (are) intended to oblige medical practitioners and pharmacists to make the patient aware of the availability of cheaper generic drugs. However, both the doctor and patient would retain the right to choose a branded product," he said.

Ntsaluba said the content of the regulations did not differ from the drug policy document released in February, a product of wide consultation with the industry.

"We don't underestimate the power of the multinational drug firms' vested interests. They ... would be adversely affected by legislation encouraging use of generics," he said.

The Pharmaceutical Manufacturers Association said the international non-proprietary names proposals made a mockery of SA intellectual property rights which included the sole right to sell and market products during the initial period of patent protection, and the "unfettered right to promote and use one's trademark". The system could also open the way for counterfeit and inferior drugs to flood the market, it said.

Ntsaluba said government had no intention of disregarding patent agreements. Greater use of generics would reduce the national drug bill.

MEDICAL AID *Anger over late payments*

Pharmacists threaten to contract out

(96)

CT (BR) 7/10/96

SHIRLEY JONES

Durban — Pharmacies around the country have banded together to demand fair play from the medical-aid industry, which is withholding sums running into billions of rands and rejecting claims for up to a year after medicines are dispensed.

The Aggrieved Pharmacists Association, which was formed by Gauteng pharmacists Julian Solomon and Nico Kriek and comprises 500 pharmacists countrywide, has issued an ultimatum to medical aids demanding fair treatment and prompt payment of claims.

The association has given medical aids until the end of this month to respond. If, as expected, there is no reply, pharmacists will consider alternative action, including contracting out of medical-aid schemes as doctors have done, forcing patients to pay upfront and to submit their own claims.

Mark Hyman, the general manager of Pharma Clinic, the recently launched managed-healthcare service, said a survey of more than 200 pharmacies in Gauteng showed that on an average day medical aids owed individual pharmacies between R275 000 and R300 000.

Medical aids' debt to pharmacies each day was estimated to total more than R7 billion, Hyman said.

He said this was in marked contrast to the industry's profit, which came to an estimated R4 billion a year.

The profit from pharmacy dispensaries alone was just R2 billion a year, Hyman said.

A spokesman for the Aggrieved Pharmacists Association said there was no means of checking client credentials with medical aids, leaving pharmacists to bear the brunt of fraudulent transactions and claims by members over their limits.

"When anything goes wrong, the pharmacist pays. The pharmacist bears the whole risk. We serve their clients and pay dearly for the privilege. They have got us over a barrel. This is not a question of profit but of cash flow," the spokesman said, pointing out that, at best, medical aids paid out after between 90 and 120 days.

Pharmacists said they had to pay wholesalers within 30 days to secure discounts and ensure that credit facilities were not withdrawn.

The association's spokesman said medical administrators, who receive their percentage payments whether medical aids pay out or not, were clearly out of their depth and did not have sufficient infrastructure to handle the claim capacity with which they were confronted.

Government backs down on drugs, dispensing issues

BD 18/10/96 (98)

THE SA government backed down yesterday over proposed health care reforms by withdrawing a key regulation after drugs firm SmithKline Beecham challenged it in court.

The Anglo American drugs firm took legal action to scrap plans by Health Minister Nkosazana Zuma which would make prescribing generic drugs mandatory and limit the dispensing of medicines.

The firm filed a submission asking the Supreme Court's Transvaal Division to fight regulation R1150, a part of Zuma's health care reforms.

The health ministry said the regulation had been withdrawn after an overwhelming response from industry and the public. "As a result of that response I have directed the department to withdraw regulation R1150 and to prepare new draft regulations which will take into account some of the comments received," Zuma said.

SmithKline said moves to limit the use of branded drugs denied doctors choice and could force them to change established patient regimens.

Generic drugs are versions of branded products that have come off patent and are usually cheaper.

The regulation also wanted to authorise (as yet undefined) licensed persons only to dispense medicine. The industry feared this could rule out many currently dispensing medical practitioners, such as dentists.

Despite the retreat, the ministry still plans to act tough with the sector. "The principles in those (withdrawn) regulations will still stand," it said.

Health department spokesman Vincent Hlongwane, who earlier yesterday had indicated a court battle appeared likely, said it was important to establish good relations with drug firms.

Hlongwane said the ministry had not yet decided what form the new recommendations would take.

The drug industry welcomed the news and struck a conciliatory tone.

SmithKline SA CE Gunter Faber said yesterday: "The industry and private health care sector look forward to working in a constructive dialogue and true partnership with government."

Meanwhile, Sapa reports that Zuma, in a reply to a question in the Senate, said all tobacco advertising would be banned if tobacco companies did not comply with existing regulations on health warnings.

She said the Rembrandt group, United Tobacco, RJ Reynolds and Imperial Tobacco were all evading the regulations. They were importing cigarettes that did not have the prescribed warnings, displaying billboard advertisements on which the warnings were invisible at night or did not show tar or nicotine content, or placed newspaper advertisements where the warnings were too small.

The health department had submitted charges laid by individuals to the police. — Reuter.

Gama, left, arrives for lunch at a Johannesburg hotel on dings MD Derek Cohen. Da Gama left SA yesterday after g his brief visit to SA. Picture: TREVOR SAMSON

Ministry's change of heart on medicine is welcomed

(96) 99

Kathryn Strachan

BD 21/10/96

THE Medical Association of SA (Masa) on Friday welcomed the health ministry's decision to withdraw controversial regulations which would have curtailed the dispensing of medicines by doctors.

Masa health policy chairman Dr Ivan McCusker said the association supported the principle of proper quality control over the provision of medicines.

"However, the proposed measures would have caused severe hardship for thousands of patients dependent on the services of dispensing doctors and in fact contradicted the objective of broadening access to health care.

"Masa applauds the health minister for her decision to take the matter under review.

"The association will put its full weight behind all the initiatives to meet the broader objective of providing comprehensive quality health services for the people of SA," he said.

The minister withdrew the proposed regulation after drugs firm SmithKline Beecham challenged it in court.

In addition to limiting the dispensing by doctors, the proposed regulation would also make prescribing generic medicines mandatory.

Despite the retreat, the ministry said the principles in the regulation would still stand. However, the ministry had not yet decided what form the new recommendations would take.

Site casinos with care, Kriel warns

BD 21/10/96

Linda Ensor

CAPE TOWN — Western Cape premier Hernus Kriel has advised bidders for the province's five casino licences to take care in selecting casino locations.

Most of the bidders have identified and bought the sites on which they propose to operate a casino if granted a licence.

Kriel said the revenue generated by casino operations would largely depend on where they were located.

He said the casinos would have to be sustained by the local population, as he did not believe international gamblers would come to Cape Town just to gamble.

"I would like to see a casino which has community facilities, provides the Western Cape provincial government with an income and looks after the social side of things.

"I would also like to see people who consistently lose large sums of money banned from the casino."

Gambling revenue flowing to the province was expected to be in the region of R15m with ancillary benefits possibly including entertainment complexes, theatres and indoor sports arenas.

Kriel said that regulations were being drawn up which would govern areas such as entrance restrictions and fees.

He said the renewed selection process for members of the Gambling Board was not a formality and that all new applications would be considered impartially.

The selection had to be repeated because of a failure to comply with the technical requirements of the legislation, Kriel said.

HEALTH REFORM

ZUMA BACKS DOWN

FM 1/11/96

Health Minister Nkosazana Zuma's eleventh-hour decision to withdraw her drug reform regulations last week rather than face pharmaceutical giant SmithKline Beecham in court, should come as no surprise.

The regulations, published for comment in July, appeared full of holes. In her rush to ban brand names from scripts,

FINANCIAL MAIL · NOVEMBER 1 · 1996

prohibit doctors from dispensing drugs and introduce a marking system for pharmaceuticals, Zuma's proposed new rules referred repeatedly to regulations and legislation "still to be published."

Understandably, the industry reasoned it couldn't be expected to comment on regulations that weren't complete and had not been properly considered by the Medicine Control Council, as the Act requires.

In papers served on Zuma, SmithKline-Beecham argued the Minister had published her recommendations "under circumstances that do not permit comments to be made thereon, or where the calling for comment was grossly unfair and not in compliance with the requirement that regulations are to be based on a recommendation of the Medicine Control Council, in that you purported to rely on recommendations which were manifestly not legitimate recommendations."

By allowing only a 45-day comment period, Zuma also ignored the provision in the Act that mandates 90 days. SmithKline announced it would seek to have the regulations declared ultra vires.

***Drugs** . . . what protection for manufacturers?*

Government advisers are understood to have told Zuma she may republish the regulations only when she can simultaneously publish all outstanding regulations since 1993 and other regulations and legislation she intends to promulgate soon, so interested parties can properly evaluate the recommendations.

Welcoming Zuma's decision to withdraw the regulations, SmithKline-Beecham CE Gunther Faber says diplomatically: "We look forward to working with the Department of Health in a true partnership to develop a robust, affordable, quality health-care system available to every SA citizen. Such a system should be developed within the macro-economic policies of the government and respect free-market principles."

Zuma may not agree. She has indicated she won't change the regulations before repromulgating them after taking account of the 300 submissions she has received in response to the July publication.

If that is the case, Zuma may face an even more interesting legal battle. Among the issues bound to be raised are whether the new rules will allow pharmaceutical manufacturers any protection of intellectual property; whether doctors will be barred from administering injections and emergency treatment and be reduced to mere diagnosticians; and whether the private sector will have to foot the estimated R1bn retail value bill that the State loses each year through poor stock controls and management in hospitals and distribution centres. ■

Medicine dispensers may soon have to charge R20 flat fee

CT (BR) 15/11/96 (96)

CHRISTO VOLSCHENK
ECONOMICS EDITOR

Cape Town — Doctors and pharmacies may be forced to charge a flat dispensing fee of R20 if the parliamentary portfolio committee on health gets its way.

They will, however, be allowed to increase their minimum consultation charge to R80 from the present R48.

The committee asked the government to "urgently remove the profit motive from the dispensing of medicine by doctors and pharmacies" yesterday and replace it with a system that allows doctors and pharmacies to charge a flat dispensing fee of R20.

The committee said a flat fee would lower the price consumers paid for medicines, in some cases by as much as 50 percent.

In a report tabled in parliament yesterday, the committee said there was "widespread support for the introduction of a flat dispensing fee in place of the profit motive" at a recent public hearing on the issue.

This was confirmed yesterday when the Medical Association of South Africa (Masa) gave its qualified support for the call, with the Pharmaceutical Society of South Africa also welcoming the call.

Edwan Stoltz, the president of the Pharmaceutical Society of South Africa, said: "The society is working with the department of health to get the flat fee implemented as soon as possible."

Braam Volschenk, Masa's legal adviser, warned that a flat fee could increase the prices of cheap medicines and should be researched further before being implemented.

The committee's call comes in the wake of the publication of the government's national drug policy in January, when it announced for the first time that it was considering "removing the profit motive from dispensing" and replacing it with "a uniform dispensing fee".

In its report, the committee said it supported the dispensing model used with great success in the Eastern Cape.

The model did not allow dispensing doctors and pharmacists to make any profit on medicines dispensed, but allowed them to charge a R20 fee and to increase their minimum charge for a consultation from the present R48 to R80.

Volkswagen's medical schemes have been successfully using the model since February.

At Volkswagen, the average value of a prescription is now R34 compared with the R147 of the medical scheme industry.

This happens because medicine manufacturers are compelled to quote prices for different medicines to a co-ordinating body, which calculates an average price from the lowest three quotes for every generic type of medicine.

The average price is then sent to doctors and pharmacists, who are compelled to sell the medicine at that price, adding only R20 as a dispensing fee. The committee said that the average price might be revised from time to time.

In this way, the cost of medicine supplied to consumers is reduced dramatically.

HEALTH AND DISEASE — PHARMACISTS

1997

Zuma sticks to her guns on dispensing

Star 22/1/97

BY MONDLI MAKHANYA
Political Reporter

(96)

The Government will this year finalise its health insurance plan and give impetus to the restructuring of medical aid schemes, Health Minister Dr Nkosazana Zuma said yesterday.

She told a media briefing in Johannesburg that her ministry would forge ahead with legislation regulating the dispensing of medicines by doctors.

The proposed bill has met with fierce resistance from doctors and other lobby groups.

But Zuma yesterday stood her ground on the matter, saying this would help prevent abuse and form an integral part of her strategy to curb the exorbitant price of drugs.

The law will allow the Government to license doctors to dispense medicines only when there is no pharmacist nearby.

She said this would discourage doctors from prescribing expensive medicines in order to boost their profit margins.

"There is a perverse incentive to prescribe expensive drugs more when there is a profit motive," said Zuma.

She said her ministry wanted to tighten up medical aid schemes in order to avoid abuse and to "make them more sustainable".

Zuma said other issues agreed to at the four-day ANC indaba were:

- The improvement of welfare payment delivery and ending corruption in the department.
- The introduction of rental stock as part of the Government's housing plan.
- An end to the eviction of squatters and farmworkers without providing them with alternative accommodation.

State to recognise role of traditional medicine

Research unit to help bridge gap

ARG 8/2/97 (96)

ADELE BALETA
STAFF REPORTER

Government recognition for traditional healers as legitimate health practitioners in South Africa will be the subject of public hearings countrywide early this year.

And in another move towards greater acceptance of the role of traditional healers, a research unit to investigate traditional medicines and to help bridge the gap between traditional healers and Western medical practitioners has been established in collaboration with the universities of Cape Town and the Western Cape and the Medical Research Council.

According to the Department of Health, at least 80 percent of black South Africans consult traditional healers.

At a recent meeting convened by the National Assembly and the former Senate portfolio committees on health it was decided that recognition, registration, medical certification and insurance for traditional healers would be top of the agenda at the hearings to be held by the Provincial Legislature's Standing Committee on Health.

National Assembly Health Committee chairman Abe Nkomo said it would be important to have hearings at a provincial level to make sure all interested parties were included.

There are 350 000 traditional practitioners compared with 300 000 Western trained health professionals in the country, according to the Health Department. But until now traditional healers, who have been campaigning for recognition for years, have largely been dismissed as 'witchdoctors', a label many shun, and their practice regarded as 'witchcraft'.

'Traditional healers have been largely dismissed as witchdoctors'

Among key issues expected to be ironed out for future policy on traditional healers are the definitions of a traditional practitioner, how he or she practices and what benefits can be expected.

There is growing acknowledgment that traditional healers are not an homogeneous group, and the provincial committees appointed to hold hearings would be required to consult with healers so as to avoid misrepresentation.

The research unit to investigate traditional medicines will be overseen by UCT pharmacology professor Peter Folb and UWC School of pharmacy professor Peter Eagles.

The group plans to create a database of traditional medicines for east and southern African traditional healers, primary health care workers, the pharmaceutical industry and the public.

Laboratory screening systems would be devised to test medicines used to combat malaria and tuberculosis in particular. Medicinal plant extracts would be investigated.

The researchers have already produced a health care handbook dealing with diseases often seen by traditional healers.

Professor Folb said that the research unit did not pretend to offer political solutions involving the role of traditional healers, but would hopefully "stimulate and inform" policy making on their future role in South Africa.

But he said this did not mean that all traditional healers were ethical practitioners. "It is well nigh impossible to separate the genuine traditional practitioner from the charlatan and consequently, to separate genuine traditional remedies from fake ones."

ROY WIGLEY

A second opinion: Medical Research Council president Dr Walter Prozesky collaborates with sangomas Jim Nbira, sitting, from the Transkei, Western Cape Traditional Doctors and Herbalists Association president Philip Kubukeli and Constance Zwane from Ladysmith

The Star ... Monday February 17 1997

Prescription drug prices to drop by 20%

(96)(183)

New cost structure, initiated by the ANC, is expected to cut costs to consumers, and has the support of medical aids and the pharmaceutical society

Star 17/2/97

By Janine Simon
Medical Correspondent

The price of prescription drugs will drop by 20% from April 1 because of a new pricing structure.

The new structure is regarded as a world first, paralleled only partially by Canadian systems.

It will replace profit markups on prescription drugs with a fixed-rand-value professional fee for dispensing, and aims to cut costs to consumers and medical aids by transparency at every point of the drug-pricing chain.

Consumers will feel the change most keenly on high-priced, new-generation drugs. For example, an oral antifungal now selling at around R150 will drop to R110, and an antibiotic selling for R182 will sell for R135.

But the total cost for a low-priced generic drug may rise by between R3 and R5, says Keith Johnson, chairman of the tariff committee of the Pharmaceutical Society of South Africa (PSA), which helped to formulate the new system.

The change will not affect over-the-counter drugs, unless they are dispensed according to a prescribed schedule.

The medical aid industry, which currently forks out 30% of its payments on drugs, is leading the cost-cutting process, says Representative Association of Medical Schemes (Rams) policy director Dr Aslam Dasoo.

Rams' first scale-of-benefits policy for medicines takes effect on April 1 and will recommend that member funds calculate the rate of reimbursements to pharmacists and dispensing doctors according to the new price structure and not the current "blue book" of prices.

The professional-fee concept originated in ANC policy, and has been thrashed out by the PSA, Rams, the Interim Pharmacy Council and the Association of Community Pharmacists, with the Health Department's support.

SA paying much more than its neighbours

It is understood that local manufacturers are supportive but multinational pharmaceuticals oppose it because the system requires manufacturers to reveal their ex-factory prices.

Township pharmacists who depend on expensive prescriptions to keep afloat, and who are in competition with dispensing doctors who trade in medicines, are also uneasy about the effect of its immediate introduction.

The new pricing structure means payment for pharmacists is no longer based on product, but on the delivery of a professional service based on specified procedures, says Johnson.

It works by adding a dispensing fee per item – figures of R15 for an acute original prescription, and R10 for a repeat prescription are suggested – on to the "reimbursement cost".

This reimbursement cost is lower than the present cost price of drugs, Johnson says. It is made up of a net acquisition price to pharmacists, to which is added a flat R3 for practice costs, and 5% to cover the cost of holding the drugs (2%), obsolescence (1%), and delayed payments and rejections by medical aids (2%).

The 2% charge will be waived if medical aids are able to pay claims within 30 days – a further substantial saving to the industry.

Dasoo says SA prices are much higher than in neighbouring countries that import their drugs.

Johnson says pharmacists, who have been battling with medical aids over discounts and late payments, are "panting" to have the system introduced.

Bada Pharasi, chief director registration, regulation and procurement, said the Health Department was mostly satisfied but would be "surprised" if Rams and the PSA did not take the situation of township pharmacies into account.

New pricing structure for drugs under attack

Star 18/2/97 (96)

Expensive drugs will drop, cheap ones rise, pharmacists warn

By Janine Simon
Medical Correspondent

The Pharmacy Manufacturers' Association (PMA) has launched a scathing attack on the new drug-pricing structure, saying that although the price of more expensive drugs would drop, the cost of cheaper drugs – which it says make up most prescriptions – will rise.

The new structure replaces profit markup on prescription drugs with a fixed professional fee for dispensing.

Pharmacies and medical aid schemes say the change will bring down the price of drugs over R37 by 20%, as was reported in The Star yesterday, but will increase the cost of cheaper drugs by between R3 and R5 per item.

According to PMA executive director Mirryena Deeb, the most frequently used prescription drugs are of the cheaper nature and that, overall, medicine bills will therefore rise. She welcomed any moves to cut the high margins in SA's drug distribution chain but said the professional fee system was "a grandiose, convoluted and potentially cost-inflationary device".

The switch from a profit markup for prescription drugs to a professional fee was thrashed out by the medical aid and pharmaceutical industries, and will be introduced from April 1.

Manufacturers, who have been accused of not wishing to reveal their ex-factory prices, were now considering publishing these prices and average discount policies in the press to allow consumers to judge for themselves whether the new system dropped prices, Deeb said. They were also considering how to make drugs directly available to patients.

Deeb added she had given an undertaking to provide all price lists and discount and settlement policies to Director-General of Health Dr Olive Shisana. The fee formula was vague and could potentially lead to abuse, she claimed. It would affect the quality of care because pharmacists would be tempted to stock and dispense the cheapest drug, she said.

Given the medical aid industry's poor track record of containing medical inflation in the 1980s, the cost of the Representative Association of Medical Schemes (Rams) setting up the administrative network for the new system could outweigh any savings. The professional fee structure also amounted to price-fixing.

Rams' new medicines benefit policy, which recommends the rate of reimbursements by medical aids, could not take into account lawful price differentiation for factors such as transport and creditworthiness. Overall, Deeb said, the system might bring short-term gains but was not sustainable.

(96)

New drug pricing scheme under attack

Star 21/2/97

Attempt to bring down prices slammed by manufacturers

By Janine Simon
Medical Correspondent

A drug fight is looming in the pharmaceutical industry as manufacturers face efforts by medical aids, pharmacists and the Government to bring down the cost of medication.

The launch of a new retail drug pricing structure on April 1 by pharmacists and medical aids is seen as a way to cut down the medicines bill of consumers and medical aids, and to encourage the use of cheaper medications.

According to the organisations involved, the effect on drug prices would depend on whether a drug was chronic or acute medication and its acquisition price, but savings to patients could be more than 20%.

But the new structure, which is based on replacing a profit mark-up on drugs with a professional fee for pharmacists, was dismissed as a clumsy attempt to avoid deregulation by the Pharmaceutical Manufacturers' Association (PMA). The PMA represents the interests of research-based pharmaceutical manufacturers, many of which are multinationals.

United South African Pharmacies (Usap) chairman Julian Solomon said yesterday the attack from manufacturers "had come as no surprise" as manufacturers' interests would be compromised if medical aid, pharmacy and government bodies were determined to reduce the cost of medication.

PMA executive director Mirryena Deeb's claim that the medical aid industry had a poor track record of containing inflation was a gross distortion, he said. Usap, which represented 1 400 community pharmacists, challenged her to publish true information on factory exit prices of drugs and the profit made on each item.

The formula that set the end price of drugs to the consumer was based on a starting price set by the manufacturer, and had not altered over the past decade.

"How can Deeb state that the lack of containment of prices was due to any player other than the manufacturers?" Solomon asked.

He said Deeb's reference to the fee formula as open to abuse ignored the fact that the current system offered dispensing doctors bonuses far in excess of, and discounts far lower than, those offered to pharmacists.

Solomon said Usap fully supported Health Minister Nkosazana Zuma's efforts to keep down drug prices.

Deeb's assertion that 60 to 70% of medications dispensed were of cheaper medicines has also been questioned. "The PSA tried to get exact figures on numbers of generic line items versus branded drugs dispensed from two of the biggest databases in the country. Both could only give figures with a 13% variance," said Ivan Kotze, executive director of the PSA.

DRUG DISPENSING (96)

PAYMENT OVERHAUL

FM 28/2/97

Consumers could benefit from a hotly debated new payment scheme for pharmacists and dispensing doctors.

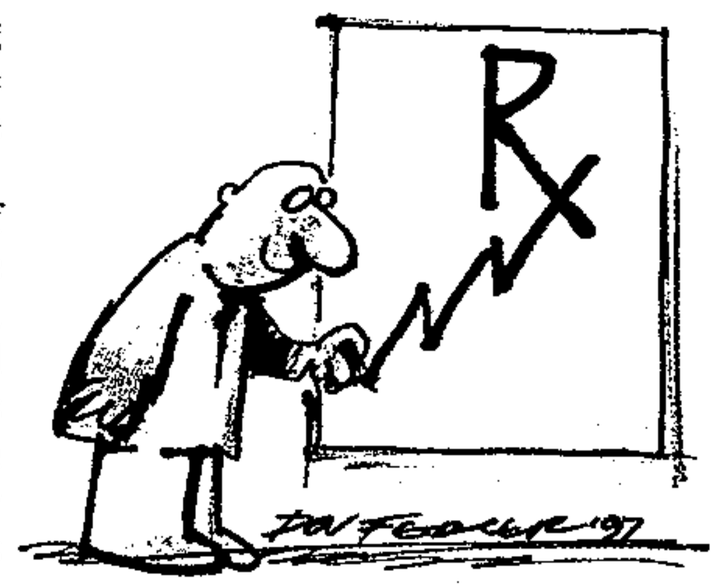
The Representative Association of Medical Schemes (Rams) will launch the scheme on April 1. Its aim is to replace fixed retail price mark-ups of about 50% with a dispensing fee of R15-R20. But it will bring little cost relief to consumers unless it's accompanied by a shift in dispensing habits.

Pharmacists' margins are a percentage of the price of medicine dispensed, which provides a perverse incentive to sell more of the expensive drugs. A dispensing fee bears no relation to the value of medicine dispensed and so should promote the use of cheaper generics.

Medical schemes spent R4,5bn on medicine last year — 28% of total expenditure of R16bn. Rams' goal is to reduce this to "internationally accepted levels" of 8%-12%, though this could take up to three years to achieve.

At current prices, a 10% price cut will save the industry R500m.

The dispensing fee is only one element of the scheme, which involves introducing a scale of benefits for medicine which Rams claims has the support of the Competition Board. Members will be paid benefits according to a formula that determines the factory exit price of a drug plus a 10% wholesale distribution charge and a dispensing fee.



In the absence of transparency in the distribution chain, Rams has assumed the manufacturer's cost of producing a drug is 17,5% below accepted norms. This puts it on a collision course with the Pharmaceutical Manufacturers' Association (PMA).

Association CE Mirryéna Deeb says the scheme amounts to to price fixing and could cause the total medicine bill to rise in the long run.

"A fixed price never represents the actual price and negates the willingness of buyers and purchasers to negotiate the best possible price."

Under the scheme, she says, drugs priced under R37 will become more expensive and those over R37 will be cheaper. As 60%-70% of all drugs dispensed cost less than R37, the overall bill could increase.

The PMA is also wary of Rams' intention to introduce a preferred drugs list. Rams spokesman Aslam Dasoo says comparable drugs will be ranked according to price and members reimbursed for the cost of whichever drug is selected as most efficacious by a medical panel, irrespective of the actual drug purchased. "This should stimulate competition and lower prices."

The notion of a dispensing fee was rejected in 1962 by the Snyman Commission because pharmacies do not monitor the consumption or prescription of medicine. In recent months, this function has been assumed by specialist companies called pharmacy benefit managers which can reap economies of scale.

How then are pharmacies to earn their professional fees? The Interim Pharmacy Council newsletter *Pharmaciae* says community and hospital pharmacies should be able to bill professional fees for evaluating prescriptions for legality, contents, appropriateness and correctness; for providing answers obtained by consulting a reference within the pharmacy, clinic or ward; for the time taken to prepare for meetings of the Pharmacy & Therapeutics Committee; or for the work necessary for the publication of a newsletter.

Rams is only prepared to accept that, in fulfilling a standard prescription, a pharmacist will follow a series of prescribed steps that will entitle him or her to a fee close to existing mark-ups.

The exact fee is still under discussion between Rams and the Pharmaceutical Society but the concept is supported in principle by the Health Department, which is overhauling the Pharmacy Act.

But cutting the cost of medicine may be better achieved by deregulating ownership of pharmacies as suggested repeatedly from the Browne report in 1985 to the 1996 Broomberg-Shisana report.

Restricting pharmacy ownership results in low turnovers and high mark-ups. Letting large retailers sell pharmaceuticals dispensed by qualified pharmacists should improve turnover and reduce mark-ups.

The Interim Pharmacy Council has yielded marginally by recommending to government that private hospitals be allowed to own pharmacies. It says lay ownership should be allowed only in communities that have no access to comprehensive pharmaceutical services.

Claire Bisseker

Health rights charter mooted to give consumers muscle

(96) Star 17/3/97

By Janine Simon
Medical Correspondent

South Africa has no effective, accessible mechanism to address complaints about health services, says Judy Fortuin, spokesman on advocacy for the National Progressive Primary Health Care Network (NPPHCN).

Fortuin said there was a broad perception that medicine was a "closed shop" and there was no redress for consumers.

"Everyone needs to be accountable, from medical aids to traditional healers," she said.

Consumers had several options: they could go to the people in charge of a facility, to the professional bodies, the Public Protectorate, Human Rights Commission, Consumer Court, the ombudsman of the Medical Association of South Africa, or the Constitutional Court.

But, said Fortuin, "we have to make sure the public knows that these mechanisms exist, pressurise the mechanisms for action and evaluate whether they are appropriate".

It was imperative that South Africa's new district health system constructed strong community health committees to protect consumers, she added.

Health commissions in countries like Canada and Australia used field officers to investigate all complaints, and even provided counselling.

The NPPHCN would put forward the concept of a health rights charter in an attempt to create awareness of the need to support consumers of health services, she added

Meanwhile, the Interim Medical and Dental Council of South Africa confirmed that its role was not widely advertised, and that only a fraction of complaints received had qualified for hearings on the grounds of professional misconduct.

An average of 1 400 to 1 500 written complaints were received a year, mostly against private practitioners, said assistant registrar Ronnie Filmalter.

Only 10% of those resulted in the doctors being charged, because investigations showed that the complaints did not warrant disciplinary action.

"This does not mean that the complaint is not valid, but that it does not warrant hauling the doctor up on charges of improper conduct," he said.

The decision to lay charges rests with a six-member committee appointed by the council, and is based on whether there is evidence of disgraceful or improper conduct. Inquiries take 12 to 18 months to finalise.

Zuma ready for battle to end drug profiteering

(96)

Some prices loaded by 4 000% in SA

ARG 21/3/97

CLIVE SAWYER
POLITICAL CORRESPONDENT

Johannesburg – Prompted by shock figures that some medicines sell in South Africa for up to 4 000 percent above the world average, Health Minister Nkosazana Zuma has vowed to bring down the cost of drugs.

Legislation to cut the cost of drugs is being checked by state law advisers and Dr Zuma intends putting it to Parliament this year. She is readying herself for a storm of opposition from vested interests in the South African medical industry.

Statistics kept by the Department of Health show that some medicines sell in this country for up to 4 000 percent above the world average. These include drugs used to treat tapeworm infestations and against hypertension. The price of some malaria prophylactics is 880 percent above the global average, while drugs for bilharzia, which is endemic in some parts of South Africa, cost about 1 575 percent more than the world average.

Dr Zuma said South Africa rated in the top five most expensive countries in the world for medicines, while being far from one of the top five richest countries.

She has vowed to find ways to cut costs "addressing the whole chain from manufacturer to retailer". Dispensers should issue the most appropriate medicine – rather than the most expensive.

On her campaign to encourage the prescription of generic medicines, she said there seemed to be a reluctance in this country to do so because of a belief that generics were inferior. But prescription of generic medicine in South Africa, at 16 percent, lagged behind that in countries like the United States, at 48 percent, and Britain, at 54 percent.

She said there should be one "exit price" for medicines, with no differences between that charged to doctors or pharmacists.

Outlining other initiatives being taken by the Health Department, she said it also supported all steps by other ministries to improve lifestyles. This meant support for steps by the departments of water affairs, housing, and agriculture, to provide clean water, nutrition, food security and generally healthier living conditions.

Steps were being taken specifically to improve women's health care, for instance, by a project to screen for cervical cancer among women in KwaZulu-Natal, where the affliction was rife. The department also intended expanding the programme of immunisation in scale and by adding new immunisations against illnesses like Hepatitis B.

It also planned a new project to hold confidential inquiries into maternal deaths that would require official reporting of each and investigation in detail.

Zuma vows to bring down cost of drugs

(96) Star 22/3/97

By CLIVE SAWYER

Prompted by shock figures that some medicines sell in South Africa for up to 4 000% above the world average, Health Minister Nkosazana Zuma has vowed to bring down the cost of drugs.

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Zuma said South Africa rated in the top five most expensive countries in the world for medicines, while being far from one of the top five richest countries. She has vowed to find ways to cut costs, "addressing the whole chain from manufacturer to retailer".

Dispensers should issue the most appropriate medicine rather than the most expensive. Those who prescribed medicine should be licensed to dispense only if their reason for doing so was in addition to the profit motive, because the ministry would not want to license them if profit were their sole motive.

On her campaign to encourage the prescription of generic medicines, she said there seemed to be a reluctance in this country to do so because of a belief that generics were inferior. But prescription of generic medicine in South Africa, at 16%, lagged behind that in countries such as the United States, at 48%, and Britain, at 54%.

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The department also intended expanding the programme of immunisation, both in scale and by adding new immunisations against illnesses such as hepatitis B. It also planned a new project to hold confidential inquiries into maternal deaths that would require official reporting of each investigation in detail, with practical steps to be taken to rectify the conditions that caused the deaths.

Vaccination coverage, at only 63% of 1-year-olds, was well below the average of 80% recommended by the World Health Organisation.

Dndle 1 – 7

'Core strength lies in professionalism'

Pharmacists warned to adapt or die

(96)

CT (BR) 1/4/97

SHIRLEY JONES

Durban — Adopting a "business-as-usual attitude" in the rapidly changing pharmaceutical industry would be to risk self-destruction, Ron Rowland, the chairman of the International Federation of Pharmaceutical wholesalers and chairman of Australian Pharmaceutical Industries, said last week.

This was because the pharmaceutical marketplace was a jungle, with slow-downs in growth, increasing government intervention, price deflation and industry consolidation, he said.

Nearing the end of a week-long visit to this country, Rowland said the pharmaceutical sectors in Australia and South Africa were remarkably similar, both in structure and value.

Four crucial areas of concern for both were falling margins, loss to supermarkets of pharmacy-only product lines, pressure on pricing and ranges from supermarkets and deregulation.

To combat falling margins, Rowland said wholesalers had had to push up sales volumes. They also had to earn more loyalty from retail customers.

To cope with supermarket competition, pharmacists had to draw on their core strength — their professionalism. He said pharmacists, trained to be health-care professionals rather than business people, had to get out into the shop and offer advice and not hide in dispensaries.

Service was the only answer as issues like supermarkets' extended trading hours were harder to match. The concept of a 24-hour pharmacy was often not financially viable, he said.

Deregulation, which would allow large retail groups to own pharmacies, was unlikely in the near future in Australia, Rowland said. The issue of professional advice and service was again paramount. The better pharmacist usually owned his own business. Larger retailers would probably be left to employ those seeking the security of salaries and not prepared to go that extra mile for a client. The larger supermarket groups also tended to be profit rather than customer driven, he said.

Rowland said there were good prospects for those in South Africa's pharmaceutical sector. A rapidly developing middle class would create opportunities for wholesalers and retailers.

He warned retail pharmacists in South Africa to avoid the trap of ordering directly from manufacturers. Direct ordering was one of the major icebergs with which wholesalers and retailers would have to contend worldwide. In the longer term it would erode wholesalers' profit structures with a knock-on effect within the retail sector.

Wholesalers ensured retailers' stock turns, carried stock on their behalf, bankrolled small retailers and provided bridging finance and provided retail back-up in the form of store displays and advertising. Direct ordering would end this and place retailers in a tough spot, he said.

Delay in new pricing structure for drugs

(96)

Some medicines are going to cost less – and pharmacy groups find that hard to swallow

Star 2/4/97

By Janine Simon
Medical Correspondent

Consumers will now have to wait until the end of the month to see any change in prescription drug prices.

A new retail drug pricing structure, which replaces profit markup on drugs with a professional fee for pharmacists, was due to be implemented on April 1.

The new system is expected to cut prices on some new-generation drugs by up to 20%.

Keith Johnson, chairman of the tariff committee of the Pharmaceutical Society of South Africa, said implementation had been postponed to April 28 because wholesalers were unable to set new systems in place before then.

Many medical aids had also been waiting for the Representative Association of Medical Schemes to issue its medicines scale of benefits.

These tariffs recommend the rate at which Rams' 185 member schemes pay members and/or pharmacists for prescription drugs, and were circulated to medical aids by fax late last week with a request to implement the new tariff structure by July.

But the rates have been rejected by the Pharmaceutical Society of South Africa, the South African Association of Community Pharmacists, United South Africa Pharmacists, and the South African Pharmacy Council because Rams had pegged the cost price of drugs at October 1996 levels.

Pharmacists could not absorb price increases since October 1996 and had started negotiations with individual schemes to "resolve the discrepancy and avoid inconvenience" to medical aid members, the pharmaceutical organisations said yesterday.

Most major administrators have already been canvassed and contracts are being prepared. Southern Healthcare JV and Sanlam medical aids were already on board, Johnson said.

"Rams is an irrelevant arbiter of pricing," he added.

Rams policy director Dr Aslam Dasoo said the new tariffs could not be enforced, but that Rams had set prices at levels which medical aids could afford.

"Medical aid members who are confused about the rate at which their funder will reimburse should call the fund to clarify," he said.

Health Minister Nkosazana Zuma, left, opened pharmaceutical group Novartis SA's upgraded manufacturing facility in Spartan, Kempton Park yesterday. With her were Novartis SA president Lothar Ehrhardt, right, and Zuma's adviser, Ian Roberts. Picture: Tyrone Arthur

Govt 'duty-bound to use generic drugs'

(96)

Ingrid Salgado

BD 15/4/97

HEALTH Minister Nkosazana Zuma issued a strong message to pharmaceutical companies yesterday, saying they needed to accept that government had a duty to use generic medicines to make health care more affordable.

Zuma's comments follow last year's legal challenge by pharmaceutical manufacturer SmithKline Beecham to regulations that would make prescribing generic drugs mandatory. Zuma withdrew the regulations before the matter went to court, and said they would be redrafted to take account of more than 300 submissions received on the matter.

But yesterday Zuma indicated that the health ministry had no intention of backing down from the principles underlying the regulations. At the opening of pharmaceutical group Novartis SA's upgraded factory in Kempton Park, she accused "those who don't like us using generics" of creating the perception that generic medicines were inferior to patents.

Manufacturers should not differentiate between patents and generics in the production process. They were obliged to provide maximum quality, affordable medicines, she said.

Zuma reiterated the ministry's willingness to work with manufacturers and distributors of pharmaceutical products in an apparent effort to mend her rocky relationship with the industry. She urged the industry to work with her "in a complementary, and not in a confrontational, way".

The revamped facility of Novartis SA, formed by the merger of Ciba and Sandoz, cost R40m to upgrade. The plant has the capacity to manufacture one billion capsules and compressed, sugar-coated and film-coated tablets, every two shifts.

Zuma's drug stance has 'changed little'

(96) BD 17/4/97

SA DRUG companies might return to the courts for a second legal battle against health care reforms proposed by Health Minister Nkosazana Zuma, a leading industry figure said yesterday.

Last October Zuma backed down over plans to make prescribing generic drugs mandatory as Britain's SmithKline Beecham took the issue to court. A consultation process was then launched to look at possible changes to the plans.

Draft legislation put forward this week had changed little, drug makers said, and the legal battle between industry and government could resume. Mirryena Deeb, CE of the Pharmaceutical Manufacturers' Association (PMA), said companies were thinking of action, but no decision had been made.

Health ministry spokesman Vincent Hlongwane said the new proposals were put together after more than 300 consultations with the public, the drug companies and other interested parties.

He said the plans guaranteed a choice to patients between generic drugs or their brand name equivalents. "We will legislate that patients should be given the choice," he said.

Deeb said drug manufacturers were worried that the wording of the draft legislation still made the substitution of generic drugs mandatory.

"A pharmacist shall ... dispense a therapeutically equivalent medicine instead of the medicine prescribed ... unless expressly forbidden by the patient to do so," the draft read.

Deeb said the use of the word "shall" was too close to enforcing mandatory substitution of generic medicines and said there were also worries that the legislation's definition of "therapeutically equivalent" was too broad. The act defined it as drugs having the same therapeutic effect from the same pharmaceutically active ingredients and dosages.

Deeb said that definition was loose enough to involve substituting one type of drug for another that was chemically different.

Another area of dispute that could crop up was any attack on the industry's right to promote its brand names. The global pharmaceutical industry jealously guarded its brand names. The draft stated: "No person shall sell any medicine to the state if that medicine contains the brand name in its label."

Deeb said any attack on the industry's intellectual property rights would provoke a legal fight.

The previous dispute with Zuma led to fears that international drug companies may pull out of an SA industry they see as hostile. Chief executive of German drug giant Boehringer Mannheim's SA unit Knut Seifert said: "If an industry is not welcome in a country, then companies have to think about downsizing of operations and moving into a more friendly environment." — Reuter.

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Doctors have the right to reject generics

As some pharmaceutical companies lobby against SA legislation to promote generic medicines, **Simon Barber** in Washington looks at the issue's recent history in the US

(96)( ) BD 22/4/97

THE makers of the third-most commonly prescribed brand-name drug in the US tried for years to suppress research showing cheaper generic equivalents of the same medicine to be equally effective, it was disclosed last week in the authoritative Journal of the Amercian Medical Association (Jama). The result might have been several billion dollars in unnecessary extra costs to patients and taxpayers, the journal said.

The disclosure comes as pharmaceutical companies have mounted an intense lobbying campaign against efforts by SA's health ministry to promote use of generic drugs in favour of more expensive branded products. Executives from at least one US company have hinted darkly — but off the record — that they may even feel obliged to disinvest from SA if the Medicine and Related Substances Control Amendment Bill passes in its current form.

A key purpose of the legislation is to lower the cost of drugs in SA, particularly those purchased and distributed at public expense, by defeating what the authors clearly see as the cartelist tendencies of the industry. On the face of it, the intention is to open the makers of brand-name medicines to greater competition.

One way the bill would do that is to permit "parallel imports" — that is, to allow wholesalers to obtain products from the cheapest sources.

The industry charges different prices to different countries. The differentials are not driven solely by a humanitarian desire to give people access to medicines they might otherwise not be able to afford.

If a multinational has invested in manufacturing capacity in a country, it will not want goods manufactured more cheaply at its plant in another country to undercut that investment.

Naturally, it will not look kindly on parallel traders or arbitrageurs playing the price differentials by buying a product destined for a low-price market and reselling it competitively in one where prices are set higher to protect local investment.

US companies argue that by permitting such transactions, SA would be violating their World Trade Organisation-recognised rights to control the marketing of their intellectual property.

A second means by which the SA legislation attempts to increase competition within the pharmaceuticals markets is to encourage the use of generic medicines with essentially the same active ingredients and pharmacological effects as the brand name varieties, but does not have to reflect developmental, marketing and other such costs in its pricing.

The pros and cons of generics are difficult for the layman to evaluate fully. It is, however, difficult to trust brand-name manufacturers entirely given the case reported in the latest Jama.

The case involves Synthroid, a synthetic form of levothyroxine, a hormone produced by the thyroid gland.

It is used to treat thyroid deficiency, a relatively common condition, especially among women. There are more than 8-million users in the US. Symptoms of the deficiency include lethargy, stiffness and low tolerance of cold.

Made by New Jersey-based Knoll Pharmaceutical, a unit of BASF AG, Synthroid commands 80% of the American market for the hormone, which is also available far more cheaply in another brand-name form — Levoxyl or Levoxine — and as a generic.

In 1987, Flint Laboratories, which then owned the Synthroid brand, gave Betty Dong, a pharmacy professor at the University of California in San Francisco, a $250 000 grant to perform a study which the company, and Dong, believed would confirm Synthroid's superiority over the other varieties.

To her surprise, Dong found that in both laboratory and human trials, Synthroid's effectiveness was indistinguishable from the Levoxyl/Levoxine and the two generic varieties that she used in her comparison.

By the time Dong finished her research in 1990, Boots Phamaceuticals had taken over Flint and Synthroid. For the next four years, according to an editorial in Jama, "Boots waged an energetic campaign to discredit the study and prevent publication of the draft Dong and her colleagues had sent them for comment, claiming that the study was seriously flawed".

Boots had begun to get nervous about Dong's work in early 1989 when the state of Massachussetts — which has medical policies that are particularly influential — was considering adding a competitor's product to its official formulary. After the company received her results, it tried to get her to reconsider them, and when she refused, took the case to her superiors at the California university, which investigated the matter and concluded that Dong's research had been rigorous and that Boots's complaints were "harassment".

The university agreed that Dong should publish her findings. A paper, by herself and six colleagues, was submitted to Jama in 1994. After sending it out for peer review, the journal decided to publish.

Suddenly the university withdrew its support. In undertaking the research, Dong had signed contract language binding her to confidentiality. Boots, by now in negotiations to sell out to BASF and clearly terrified that any threat to the near-monopoly of Synthroid would reduce the company's value substantially, threatened to sue if her research became public.

The university, fearing massive damages, became scared and said it would not back Dong in litigation.

The paper was withdrawn.

The sale to BASF went through in 1995 and Boots was folded into BASF's US Knoll subsidiary. In a bid to put a stake through Dong's work, a Knoll scientist, Gilbert Mayor, published an article asserting Synthroid's virtues and trashing Dong's work, even though it had not been published. As Jama noted this week: "The article by Mayor was published in a new journal, the American Journal of Therapeutics, of which Mayor was an associate editor."

Meanwhile the US Food and Drug Administration (FDA) had taken notice. It had come to suspect that Mayor was a shill for Synthroid.

In 1994 it wrote to Boots asking it to stop disseminating a 1992 article by Mayor asserting the product's "pharmacokintetic superiority" over rival medicines.

Last November, according to Jama, the FDA turned even tougher. It told Knoll that it was violating the law by "misbranding" Synthroid. That was enough for Knoll president Carter Eckert, who agreed not to interfere with Jama's publication — finally — of Dong's findings. He submitted also a letter apologising for blocking Dong's manuscript, which Jama published in the issue released on Wednesday, along with a lengthy editorial recounting the sordid saga and asserting confidence in Dong's work. Knoll was given space for a brief rebuttal.

Dong's article included a claim — which Jama thought valid enough to stress in its editorial — that Synthroid's scientifically unwarranted market dominance was causing the public to be overcharged by as much as $350m a year. Jama published, too, a study citing numerous other instances of drug companies trying to quash unfavourable research findings.

Does this mean that all generics are equal to brand name drugs? Not at all. What it does say is that the claims of the brand name makers have to be treated with a little healthy scepticism — an observation borne out by some of the lobbying against the SA legislation.

Talking points against the bill prepared by the hugely powerful Pharmaceutical Research and Manufacturers of America — Pharma, as the lobby is commonly known — contend that it calls for "mandatory generic substitution" which poses "a potential threat to patient saftey if the substituted medicines of inferior quality".

Whether or not that "threat" is real, the draft itself contains no provision for "mandatory" substitution. It specifically grants both doctor and patient the right to say no to generics.

MEDICINES AMENDMENT BILL

96

Generic battle looms

FM 25/4/97

Minister Zuma would like to make generic medicines mandatory

Health Minister Nkosazana Zuma's mention last month to the Conference of Editors of statistics which claim medicine in SA is 4 000% more expensive than elsewhere, precedes the tabling in parliament of sweeping new drug reforms.

The draft Medicines & Related Substances Control Amendment Bill is Zuma's attempt to make medicines more affordable.

The multibillion rand pharmaceutical industry is considering renewed court action to halt the draft Bill, which effectively introduces mandatory generic substitution. A generic drug is a chemical equivalent which is cheaper by virtue of the patent on the original having expired.

In October 1996 Zuma backed down over plans to make the substitution of generic medicine mandatory when British multinational SmithKline Beecham took her to court. The dispute prompted fears that international drug companies would disinvest.

Nkosazana Zuma

Last week Zuma publicly vented her feelings towards drug manufacturers when she rounded on members of the Pharmaceutical Manufacturing Association (PMA) who requested a meeting to discuss the statistics, saying: "3 000%, 4 000%, 5 000% — what difference does it make what prices I quote? We are one of the five most expensive countries in the world."

But PMA executive director Mirryena Deeb claims that manufacturers are not to blame for SA's high medicine prices and that Zuma's statistics are "intellectually dishonest."

She claims they compare local private sector retail prices with the prices of the International Dispensary Association (IDA), a Dutch aid organisation which sells cheaply acquired generic drugs to developing countries. In fact, some of the PMA's members have donated drugs to the IDA.

They also ignore the fact that local manufacturers supply drugs in bulk to the State at tender prices which are sometimes a tenth of the price at which they are released to the private sector.

Deeb accuses the health department of keeping under wraps statistics which show that on average local State tender prices are lower than Unicef prices. Unicef has a commercial buying arm which purchases medicine for aid purposes.

Deeb lays the blame for SA's high medicine prices on the retail structure and the distribution chain where mark-ups of 100% on factory exit prices are not uncommon. In the US the average mark-up is 25%.

The Bill, soon to be tabled in parliament, attempts to make medicine more affordable. The key proposals are:

- Generic substitution. The Bill says: "A pharmacist shall prescribe a therapeutically equivalent medicine instead of the medicine prescribed by a medical practitioner . . . unless expressly forbidden by the patient."

  Generic prescribing and substitution is accepted international practice but is seldom mandatory. Detractors say the wording of the Bill amounts to mandatory substitution and fear it could also result in chemically different drugs being used interchangeably;
- A near ban on dispensing doctors. The proposal that only licensed practitioners may dispense was the subject of heated public hearings in parliament last year and will again be fiercely resisted;
- The registration of essential drugs will be expedited. The Bill does not say on what criteria registration will be based;
- The introduction of parallel imports — drugs which may be cheaper by virtue of being sourced from other countries; and
- A ban on the sale to the State of any medicine containing a brand name in its label. Deeb says the industry will fight in court any attack on its intellectual property rights.

Claire Bisseker

PHARMACEUTICALS

Zuma's favoured drug house accused of dumping

Health Minister's controversial bargain basement deal comes back to haunt her

FM 25/4/97 (96)

The Board on Tariffs and Trade has slapped provisional duties on Indian pharmaceutical giant Ranbaxy for allegedly dumping medicine in SA.

The generic medicine is part of a State tender contract the multinational won in controversial circumstances last year.

BTT investigators visited Ranbaxy's New Delhi offices in January. A preliminary investigation found that the tender prices at which Ranbaxy's two generic forms of penicillin, ampicillin and amoxycillin, are being supplied to SA constitute dumping. They are being sold to government below prices they would reach on the tender market in India.

***Dr Pravinder Singh** . . . Ranbaxy chief and generics guru*

The report concludes Ranbaxy is damaging the local pharmaceutical industry and, in particular, a rival for the tender contract, Pharmacare (part of SA Druggists), which initiated the probe.

Ranbaxy has hit back strongly, accusing Pharmacare of selling the same products on the domestic private market at prices lower than the tender award.

Ranbaxy SA director Terry Lee says proof of this has been supplied to the BTT. He says Ranbaxy can prove it is not dumping and will challenge any finding to the contrary.

Ranbaxy caused an uproar by winning the bulk of the R121m State antibiotics tender in June 1996 after the Medicines Control Council expedited registration of the two generics.

The furore coincided with the breaking of Health Minister Nkosazana Zuma's *Sarafina 2* financing scandal and Ranbaxy was rumoured to be the mystery donor, an allegation it and the Health Department denied.

On April 11, the BTT imposed a provisional duty of 5%-14,7% of the free on board value of four product lines of Ranbaxy's two generics. It has until May 16 to show why the duty should not be made final.

Lee says the petition by Pharmacare is against the spirit of Gatt and should not have resulted in an investigation.

He says Ranbaxy's prices in the tender are above manufacturing costs and higher than its selling prices to some countries. "Ranbaxy is able to provide medicine at a low cost without compromising quality because it's a backward-integrated enterprise which manufactures its own raw materials."

He says India's top pharmaceutical company is represented in more than 50 countries.

Ranbaxy, he adds, will absorb the duties and does not believe there will be any repercussions for the tender contract.

However, it is possible that Pharmacare could seek to have the tender contract set aside if its petition is upheld by the BTT.

The report notes that since losing the contract, Pharmacare has suffered "a loss of market share, price undercutting and suppression and a loss of sales volume and revenue, profits and production capacity usage."

Pharmacare claims that if it continues to lose orders for penicillin, production will have to be scaled down a lot, if not ended, leading to the loss of staff dedicated to the production of amoxycillin and ampicillin.

The report says the import volume of dumped ampicillin has risen from nil in 1994-1995 to 26m capsules for the 1996-1997 tender period — double projected domestic sales volumes and more than five times Pharmacare's projected sales for the period.

Pharmacare financial director Derrick Jones says Pharmacare is pleased with the outcome of the investigation but does not wish to comment until after May 16 in case the order is not ratified.

Claire Bisseker

Govt targets wastage, cost of drugs

(96)

By Jovial Rantao
Political Correspondent

Star 28/4/97

Cape Town – The Government is to institute measures aimed at putting an end to the wastage of drugs through fraud and theft and would pursue means to reduce the cost of drugs, Health Minister Dr Nkosazana Zuma has announced.

Zuma told Parliament on Friday during a debate on the health budget, that the anti-fraud and anti-theft measures, to be introduced in all provinces, would save the Health Department up to R500-million, which would be used to improve funding for health care in other areas.

"The wastage of drugs through theft and fraud will be cut by enforcing bar-coding to track distribution and by issuing essential, primary health care drugs in patient-ready packs.

A new information and billing system is being introduced into public hospitals to improve administrative efficiency.

"Hardware for the new system will be in place in the Northern Province, Mpumalanga, Free State, Gauteng and Northern Province by the end of the year and staff training will be well advanced.

"Progress is being made in the Eastern Cape and KwaZulu Natal, and the Western Cape will expand existing systems provided funds are available," Zuma said.

This year, she added, the Health Department would massively increase access to affordable high-quality medicines.

"South Africa has been paying too much for its medicines. Through improved drug procurement and distribution we will ensure that safe and effective drugs are secured at the lowest cost. We're introducing legislation to control and regulate medicines and related substances.

"We're introducing legislation to increase access to pharmacies so that medicines can be distributed by pharmacists working in a variety of outlets. This will give people greater choice and introduce an element of competition which will keep prices down," Zuma said.

Free fluoride tablets provided to children

*3. Dr R RABINOWITZ asked the Minister of Health: [Written Question No. 635.] (96)

Whether, in view of the fact that ingested fluoride is of value only to children between the ages of eight months and 11 years and may cause cancer, bone deformity and depressed immunity in individuals ingesting large quantities of fluoride in drinking water, she or her Department has considered a programme for providing free fluoride tablets to children between the ages of six months and 11 years at schools and clinics; if not, what is the position in this regard; if so, what are the relevant details? N1075E

The MINISTER OF HEALTH:

Firstly, I would like to reply to the first section of the question and give some background information about the real facts regarding water fluoridation.

Children benefit the most from water fluoridation. During the formation period of the teeth, fluoride strengthens the tooth structure and increases the resistance of teeth to acid (formed by bacteria in plaque and sugar) attack. Adults also definitely benefit from water fluoridation. When getting in touch with the surface of teeth, the fluoride prevent tooth decay of incipient lesions through a process of remineralisation. It also prevents root caries in adults with receding gums.

There is no scientific evidence that water fluoridation at optimum levels (about 1 part per million or 1 mg fluoride per litre of water) cause cancer, bone deformity or depress the immune system. The question refers to large quantities of fluoride in drinking water, which is not the intention with the planned water fluoridation programme. Any trace element like fluoride, iron or zinc is harmful to the human body if taken excessively.

Yes, alternatives like fluoride tablets have been considered. However, these programmes are too expensive. The wholesale price of fluoride tablets are about R30,00 for 400 tablets. That is 7,5 cents per tablet. Depending on the natural fluoride levels of drinking water and the age of the child, 2 to 3 tablets will have to be taken every day. That will add up to R150 per day to cover only 1 000 children taking 2 tablets a day. Apart from that this strategy being too expensive, not all children attend clinics. Furthermore, studies have shown that tablet programmes, even at schools, are not that effective, because on average children only attend about 200 school days per year. Studies have also shown that supervisors to these programmes are not committed in ensuring that children take the tablets daily. All these factors taken into account prove that a fluoride tablet programme is not as effective.

Research has shown that water fluoridation is still the safest and most cost-effective way in reducing dental decay. It is 18 times cheaper than toothpastes, and 61 times cheaper than filling a tooth.

Community health: international donor funds for NGOs

*4. Dr R RABINOWITZ asked the Minister of Health: [Written Question No. 636.]

Whether, in view of the role played by commmunity health workers in the home care of patients with tuberculosis and Aids, she or her Department intends acquiring international donor funds for non-governmental organisations involved in community health work; if not, why not; if so, (a) according to what criteria will the NGOs which are to receive funds be selected and (b) how will such NGOs be linked up to willing donors? N1076E

The MINISTER OF HEALTH:

None. Our policy on community health workers is that each Province considers its own needs and uses health workers appropriately.

Our policy on donor funding is to encourage projects that are sustainable and not dependent on donor funds.

Secrecy surrounding HIV/Aids removed

*5. Mrs J N VILAKAZI asked the Minister of Health: [Written Question No. 665.]

Whether she or her Department intends pursuing a policy aimed at removing the element of secrecy which surrounds HIV/Aids; if not, what is the position in this regard; if so, (a) what are the details of such policy and (b) how will her Department deal with (i) pre-employment testing for HIV/Aids, (ii) the testing for HIV/Aids of prisoners and patients in public care facilities, (iii) the testing of patients by doctors and (iv) the protection of families and sexual partners of individuals applying for property loans and insurance policies and who are tested HIV/Aids positive? N1155E

The MINISTER OF HEALTH:

No, the Department of Health is in the process of appointing a consultant to develop various policies, including a policy on confidentiality. We consider the issue of confidentiality as an important human rights issue. However, confidentiality is distinct from secrecy and the policy will seek to destigmatise and 'normalise' HIV/AIDS whilst at the same time protecting the rights of infected persons to privacy (as defined in the Bill of Rights).

(a) and (b) fall away.

Medicines imported from abroad

*6. Dr R RABINOWITZ asked the Minister of Health: [Written Question No. 666.]

(1) Whether her Department intends importing medicines from abroad; if so, (a) to what quality controls will such medicines be subject and (b) who will bear the costs of returning so-called "call back" batches of medicines;

(2) whether these imports will be taxable; if not, what is the position in this regard; if so, what are the relevant details;

(3) whether such medicines will be subject to the same quality and registration controls as local products; if not, what is the position in this regard; if so, what are the relevant details? N1156E

The MINISTER OF HEALTH:

(1) Yes.

(a) The same quality controls that apply currently to medicines brought into the country will apply. Standards will not be lowered.

(b) It must be noted that many applicants for medicines registered with the Medicine Control Council (MCC) are merely distributors who do not manufacture the products locally, but import them as finished products. The applicant, who has to have a local physical presence, is responsible to the Council for any problems with call-back or others related to quality. This will not change.

(2) Parallel imports will be treated in exactly the same manner as all other imports.

(3) Yes. Locally manufactured products, as well as finished products that are imported, are subjected to a rigorous evaluation process. Mechanisms currently employed by the MCC of quality, safety and efficacy, apply to new chemical entities. Medicines that have already been evaluated for efficacy and safety require on-going assessment for quality, which is through compliance with Good Manufacturing Practice, stability and all other requirements in the validation process. All this will apply fully to parallel imports.

Chiropractors/homeopaths/others: ethical criteria

*7. Dr R RABINOWITZ asked the Minister of Health: [Written Question No. 667.]

(1) Whether the Chiropractors, Homeopaths and Allied Health Service Professions Interim Council has laid down ethical criteria, to which members must adhere, in respect of (a) the enforced labelling of products and (b) a pricing standard for consultations and treatments; if so, (i) what criteria in each case and (ii) to what body are members accountable if they contravene such criteria;

US pharmaceutical companies to tackle Zuma on proposed bill

(96) BD 2/6/97

Simon Barber and Ingrid Salgado

US DRUG companies plan to make the issue of Health Minister Nkosazana Zuma's draft Medicines and Related Substances Control Amendment Bill a hot issue when Deputy President Thabo Mbeki arrives for the US-SA Binational Commission next month.

Zuma would accompany Mbeki and address the companies' concerns, her office said yesterday.

This follows the launch of an offensive by US drug companies against the minister's planned legislation aimed at curbing the local cost of medicines.

They have taken their complaints to Congress, the White House, the commerce department and the office of the US trade representative. They have also enlisted the support of the International Trademark Association.

Their chief objections are laid out in talking points prepared by the industry's powerful Washington trade association, Pharmaceutical Research and Manufacturers of America (Pharma).

The companies' cause has also been taken up by the US-SA Business Council, which serves as the secretariat for the business committee of the US-SA Binational Commission chaired by Vice-President Al Gore and Mbeki.

Last week, council chairman Aldrage Cooper, a Johnson & Johnson executive, wrote to Commerce Secretary William Daley urging him to raise the intellectual property issues directly with senior SA officials.

The firms' single most serious grievance is not over the bill's efforts to promote the use of generic, as opposed to brand name, drugs, but over the blessing the draft appears to give to "parallel imports".

The bill would permit importers "in certain circumstances" to buy brand-name drugs outside the manufacturers' own marketing networks in order to exploit the wide differences in what the multinationals charge for their products in different countries. Pharma argues this would violate the World Trade Organisation's (WTO) trade-related intellectual property agreement which, the association says, confers on patent holders the "exclusive right" to control marketing and distribution.

Pharma says that on top of violating SA's own WTO commitments, allowing parallel imports would cut into local manufacturers' sales, leading to losses in tax revenue and jobs, and diminishing technology transfer.

Other issues Pharma raises concern the bill's proposal to forbid the use of brand names of drugs as their "legally

Continued on Page 2

Zuma

(96) BD 2/6/97

Continued from Page 1

approved" names in the official formulary, and a provision which states that no person "shall sell any medicine to the state if that medicine contains the brand name in its label".

Both measures are attacked as "unjustified encumbrances" on the use of trademarks in terms of the WTO intellectual property agreement. On Friday, the International Trademark Association endorsed these complaints.

British-American pharmaceutical group SmithKline Beecham would be reluctant to invest further in SA should Zuma's proposed wide-ranging changes to the industry be made law, CEO Günther Faber has said.

Johnson & Johnson said at the weekend that although it had not yet considered whether to halt further investment by its local pharmaceutical arm Janssen-Cilag, it was "deeply concerned" about the legislation.

A ministerial spokesman said the complaints were "premature" as their concerns could be taken care of during submissions on the proposed laws at public hearings due this week in Cape Town. There was "ample scope" for the legislation to be amended.

The Pharmaceutical Manufacturers' Association, Pharma's local counterpart, said a legal challenge would be considered if the legislation was adopted in its current form.

Bill 'will drive pharmacists out of work'

BD 2/5/97 (96)

Wyndham Hartley

CAPE TOWN — Potentially controversial changes to the Pharmacy Act, which among other things will allow nonpharmacists to own pharmacies, has been tabled in Parliament by Health Minister Nkosazana Zuma.

The Pharmacy Amendment Bill will also change the composition of the Pharmacy Council and give it increased powers to dismiss and appoint registrars of the Pharmaceutical Council and to delegate its powers to committees and co-opt professional boards.

Democratic Party health spokesman Mike Ellis, who has been warning of conflict between Zuma and pharmacists, said there was deep concern in the industry about section 22 of the bill, which would take ownership of pharmacies out of the hands of pharmacists. This would allow large corporations such as Clicks and Pick 'n Pay to dominate the industry and drive retail pharmacists out of business, with a

Continued on Page 2

Pharmacy Act

(96)

Continued from Page 1

BD 2/5/97

consequent loss of skills.

Ellis said he was particularly concerned about the fact that Zuma had not undertaken negotiations with the pharmaceutical industry. Pharmaceutical Association members were at this late stage not sure which of three drafts of the bill had been tabled.

He said the bill also gave increased powers to Zuma. In the past, the minister had been required to follow recommendations of the Pharmaceutical Council, whereas the new legislation provided that she need only consult it.

Ellis said Pharmaceutical Council members would find themselves in a difficult position if the legislation was passed, because they would be trying to make a law work which they had already suggested was unworkable.

He hoped Zuma would not do to the council what she had done to the Nursing Council, whose composition she had changed despite an agreement with nursing unions.

PLAN TO CUT MEDICINE PRICES

Zuma unleashes drugs furore

CT 7/5/97 (96)

DRUG companies say Health Minister Nkosazana Zuma's plan to import medicines cheaply will be unfair competition and may open the door to unsafe products. Health Writer **CAROL CAMPBELL** reports.

HEALTH Minister Dr Nkosazana Zuma has provoked a furore in the pharmaceutical industry with her plan to import medicines quickly and cheaply to cut the bill for public health.

Zuma's move is aimed at providing cheap but effective medicines to the poor — but pharmaceutical giants say it will represent unfair competition as they are required to abide by strict quality and registration controls.

In an interview from Geneva, the chief executive of the Pharmaceutical Manufacturers' Association, Mrs Mirryena Deeb, said yesterday that local pharmaceutical companies welcomed international competition, provided they had an equal chance to win government business.

"International competition will hurt us, but we welcome it. However, we insist that drugs brought into this country by the state be subject to the same controls (as) our medicines."

The Cape Times has established that the state buys medicines on local tender, which means the cheapest South African supplier acquires stock and sells it to the government for about one-tenth of the price for which it is sold in the private sector.

Using a hypothetical example, Zuma might be paying R5 for 100 Panado pills in the state tender system. If she buys the same drug overseas, she could pay as little as R1,50 for 100 pills.

If Zuma succeeds in pushing through changes to legislation that will allow her to import drugs, this could open the door to the risk of buying cheap drugs that have been dumped by overseas companies.

Imports by the government would undermine the strength of local pharmaceutical giants, which could lose millions if their traditional market is flooded with cut-price drugs.

"The government must consider the sustainability and reliability of its sources before it commits itself," Deeb said. "What happens if a batch is called back — who will foot the bill for massive losses?"

The health minister's main gripe with pharmaceutical companies is that they will not give her a proper breakdown of who makes how much in the medicine supply chain.

Mrs Precious Matsoso, medicines director for the national health department, said it was understood that the price was marked up by wholesalers by 17,5% and pharmacists by 50%. Discounts negotiated with manufacturers were seldom passed on to the consumer.

"We want the pharmaceutical industry to be transparent about price structures — all we know about how medicine prices are made up is what they tell us," Matsoso said.

Pharmaceutical manufacturers did not argue this point, but said the quagmire in prices arose in the distribution and resale of drugs.

Allowing businessmen to open pharmacies and employ pharmacists to run them would help to bring down prices as drugs would move into untapped markets. Only pharmacists are allowed to own pharmacies — and most of these are in oversupplied communities. Many pushed up their prices as their market was too small to allow them to make profits by selling large quantities, the manufacturers said.

Dr Gunther Faber, chief executive of SmithKline Beecham International: Southern Africa, said that by buying overseas, the state could unintentionally facilitate imports of counterfeit medicines or the growth of a "grey market".

"The World Health Organisation estimated that about $12 billion (about R53bn) in counterfeit medicine a year finds its way into the developing world. Unfortunately, unscrupulous individuals dealing in counterfeit medicine have caused the deaths of numerous people."

Matsoso, too, was adamant that quality had to be maintained, but said medicines were useless if most people did not have access to them.

Mr Barney Sachs, executive director of the National Association of Pharmaceutical Manufacturers (NAPM), said a study two years ago had found that local tender prices in the public sector were among the lowest in the world.

"We can compete," he said. "In accordance with the minister's thinking, we need to have a strong local pharmaceutical manufacturing industry that will not only provide the local market with high-quality products at affordable prices, but could also ... export ... medicines to the north."

Sachs said the NAPM was not opposed to competition, provided it was structured fairly.

"We are against the dumping of medicines on the market," he said.

Matsoso said a large amount of the money pharmaceutical companies made was spent on researching and developing new and better drugs.

"We have to find a balance as there is no point coming up with better drugs when the majority can't afford them."

Faber said the research-based pharmaceutical industry spent about 20% of its annual turnover on research and development.

"Without this research and development — conducted within the private sector — diseases like Aids and TB will never be conquered."

Professor Peter Folb, chairman of the Medicines Control Council and director of the WHO Collaborating Centre for Drug Policy, supported Zuma's move to

❒ Turn to Page 3

Importing drugs 'has pitfalls'

❑ From Page 1

make medicines affordable for the poor, but warned that the quality of medicines coming into the country had to be watched closely.

Before the government decided to import medicines, Folb said, it would be advisable to look at the pitfalls experienced in Africa.

"A survey of 42 countries in Africa (excluding South Africa) found that for every $100 (about R445) spent on sourcing drugs for the government, patients received only $10 (R44,50). At least $90 (about R400) was lost through waste, theft and inefficiency," Folb said.

In South Africa, individuals had been allowed to make enormous profits selling medicine and Folb said he agreed with Zuma that this had to be stamped out. The prices charged for a drug differed by as much as 1 000% among some dispensing doctors.

Matsoso said consumers in the US were also becoming agitated with the high cost of drugs. "They want pharmaceutical companies to find other ways to fund their research and development so the price of drugs can come down. (The US) is a wealthy nation, so how can we expect people in South Africa to afford these high prices?"

In South Africa, an estimated R24bn is spent every year on health in the public and private sector, of which R8bn is spent on medicines. Of the R8bn, R5bn is spent in the private sector — which treats 20% of the population — and R3bn by the state.

Another bone of contention within the government is whether it should charge VAT and duty on imported medicines.

Folb said the national Drug Policy Committee had suggested to Zuma that taxes be dropped on essential medicines, but this had not been followed up. "The question now is: will the state tax its own imports?"

(96) CT 7/6/97

Opposition to medicines bill heats up

(96)

BD 12/5/97

Kathryn Strachan

PHARMACEUTICAL manufacturers are, as a last resort, considering legal action to fight Health Minister Nkosazana Zuma's new medicines legislation, which gives her wide control over drug pricing.

The Medicines and Related Substances Control Amendment Bill, introduced in Parliament last week, enables her to force pharmacists into line with her national drug policy.

The Pharmaceutical Manufacturers' Association said the proposals amounted to "nationalising the industry" and violated foreign investors' intellectual property rights.

"These are wide and undefined powers the minister is trying to give herself so she can intervene in trade matters such as advertising and marketing, when she should be confining herself to issues of ethics and safety, and ensuring access and affordability," said association president Mirryeena Deeb.

The association would make representations at parliamentary hearings next week and try to convince the minister that her proposals would scare off foreign investors and do nothing to help achieve her objectives.

"If all else fails we will consider legal action," Deeb said.

While the association recognised the important role of generic substitution within a competitive environment where the patient had a choice, it was against making generic substitution mandatory. The proposals making substitution compulsory unfairly favoured one group above another, she said.

The association would also fight the proposal allowing parallel importation, which enabled the health department to buy abroad drugs identical to ones made in SA. While the association was not opposed to international tendering or imports, parallel importation went against drug trademarks registered in SA, she said.

The Medicines Control Council said parallel importation would open new avenues for imports of fake and potentially toxic drugs.

Deeb said the Pharmaceutical Manufacturers' Association welcomed international tendering, provided the same registration requirements held for all tenders. It opposed the bill's "fast-tracking" proposal, which would allow registration of selected drugs within a few weeks. The department had not explained how this process would operate. Another concern was that health care standards could be compromised by short-circuiting registration requirements.

The proposal that medicines sold by manufacturers to the state not be allowed to carry their brand name was a further contravention of trade rights. "This is a non-negotiable for us and a serious violation of the intellectual property rights of foreign investors."

Deeb said manufacturers were concerned about mark-ups applied along the pharmaceutical distribution chain, which in cases ran as high as 400%. They would welcome genuine efforts to limit these mark-ups.

A heated argument broke out recently over Zuma's contention that SA drug prices were 4 000% higher than in other countries. Deeb countered that the minister was comparing prices offered to aid organisations such as Unicef with private retail prices in SA.

Opposition bid to halt push on health bills

Parties united

CLIVE SAWYER
POLITICAL CORRESPONDENT

(96)

ARG 13/5/97

Five opposition parties are trying to block government attempts to push a series of major and controversial health bills through Parliament before the winter recess in July.

Spokesmen for the Democratic Party, the Inkatha Freedom Party, the National Party, the Freedom Front and the Pan Africanist Congress said in a joint statement that the bills had far-reaching implications for the sale of pharmaceuticals.

At issue are the Medicines and Related Substances Control Bill, the Medicine, Dental and Supplementary Health Service Profession Amendment Bill and the Pharmacy Council Bill.

The bills would also have a serious impact on the roles of the Medical and Dental Council and the Pharmaceutical Council. Discussion of the white paper on reforming the health-care system should be completed before the bills were processed, the party officials said.

"If adequate time for public debate and wide consultation on these bills is not provided for, the passage will represent a mockery of the so-called transparent and consultative parliamentary process."

Mike Ellis, DP health spokesman, said the Health Ministry was trying to push through the bills "in unprecedented haste".

All three bills deserved full and open public hearings before extensive debate in the health committee, he said.

"Yet each bill has been allocated only one morning's hearing, and then on consecutive days. It is obvious that no committee can do justice to three important bills at the same time, and that normal procedure, of dealing with one bill at a time through to finality, should be employed."

Zuma's medicines proposals are logical

Plans to alter drastically the regulation of medicines in SA have caused a furore. David Harrison takes the pulse of the health sector

BD 15/6/97 (96)

HEALTH Minister and everybody's favourite ogre, Nkosazana Zuma, is at it again. Her latest legislative foray pits her ministry against the big guns of the pharmaceutical industry in a struggle of Herculean proportions, if international experience is anything to go by.

Two bills related to the oversight and control of medicines have just been tabled in Parliament. The Pharmacy Amendment Bill raises a few hackles by shifting the issuing of pharmacy licences from the pharmacy council to the health department, and opening the ownership of pharmacies to anyone other than a medical doctor. However, this bitter pill is sweetened a little for private hospital pharmacists, who will now be able to practise as part of a team of health professionals.

But the bill that really makes many pharmaceutical manufacturers spit is the amendment to the medicines and related substances act.

If health reform is all about solving puzzles of varying complexity, then the regulation of medicines is its Rubik's cube. There are many elements that need to be aligned with one another. Some moves may only alter the relationship of one element to another without taking us any closer to a coherent final picture.

Because of this complexity, there are numerous stakeholders and interest groups, each looking at the problem from a different angle. Few of us, if any, can claim to be dispassionate observers, so I make no claim to fall into that category, but the proposals make sense to me as a consumer with a particular interest in the development of health care in SA.

Like Rubik's cube, moves to improve medicines control require a methodical approach. This should be guided by two principles: first, the aim of it all should be to improve health, a goal easily missed in the fracas. Second, the public and private health sectors in SA must be regarded as part of one system, not two.

This principle is best illustrated by example: those who can afford medical insurance often use the private health sector. Those who cannot, use public health care. So the more affordable the private sector, the more people will be able to use it and the less pressure there will be on public services. Conversely, high private medical care costs push people towards the public sector. The minister must ensure practices in both sectors enhance affordability and access to health care.

So what is the intended purpose of medicines regulation and control? It is to ensure that:

- ☐ Medicines of good quality;
- ☐ Are available at affordable prices, and;
- ☐ Are prescribed and dispensed in a logical manner.

The principal mechanism for ensuring that medicines are of good quality is the Medicines Control Council (MCC), established in terms of the original act in 1965. A welcome amendment is that the registration of all medicines will lapse after five years, providing for continuing review of efficacy and effectiveness. The scheduling of substances, which imposes controls on who is permitted to prescribe as well as methods of prescription, has also been updated.

The most substantive amendments to this act seeks to put a lid on the spiralling costs of health care, and pharmaceuticals in particular. Any subscriber to a medical aid scheme will vouch for the fact that inflation related to health care has far outstripped general price increases. In 1982, medical scheme contributions were equivalent to 7,1% of average formal sector salaries. A decade later, this proportion has doubled to 15,2%. Increases in the price of medicines have been the greatest culprit.

In real terms, medical aids now fork out twice as much per beneficiary to cover medicines than they did 10 years ago. Medicines account for a sizeable chunk of the total medical bill and to almost a third in the private sector. It stands to reason any action that caps expenditure on medicines will have a significant effect on medical inflation.

One measure used by the World Health Organisation to reduce costs considerably is the use of generic medicines. These are similar in effect and efficacy to the original medical compound and can be used once that drug's patent has expired. Generic medicines are not cheap substitutes, and the MCC ensures that those available here are dependable, safe and equivalent to the original brand name products.

Contrary to assertions, the amendment to the act does not make generic substitution mandatory. Rather, it places responsibility on every pharmacist to inform all customers when less expensive, but equally effective, alternatives to the medicine prescribed are available. Both the customer and the prescribing practitioner have the right to refuse that generic. This practice should contain costs through greater awareness of drug prices by practitioners and routine dispensing of the least-costly drug option.

The proposal to allow "parallel importation" of medicines is as contentious as generic substitution. This proposal will enable the health department to purchase the same drug from the parent or subsidiary company based in another country if the price is better. From the perspective of a government department trying to ration limited resources, this proposal makes sense. As will be noted later, there are considerations of quality control which make the option not that clear-cut.

Another measure aimed at constraining costs is a single "exit price" for each type of medicine, to be introduced as part of new pricing system and made public. Provision is made for bulk discounts.

The exit price means the price at which medicines are sold by manufacturers, and greater transparency of pricing will allow the public to assess for itself the extent of mark-ups and retail profits. Until now, there has not been an effective way to monitor and control price increases — a weakness overcome by the establishment of a pricing committee to implement a system that the average consumer can understand.

Medicines ... make up almost a third of the private sector health bill.

The third objective of medicine regulation and control is to ensure that medicines are prescribed and dispensed in a logical manner. There are SA clinics without medicines, or which receive erratic supplies. Nurses, the main prescribers in rural areas, are confronted with an often-changing array of medicines, which encourages inappropriate and wasteful prescribing. They need a limited range of medicines which deal effectively with 95% of conditions they see and treat, which they can really get to understand and prescribe properly.

Introduction of the essential drugs list in the public sector a year ago struck the most fundamental blow in favour of rational drug use in SA, limiting the number and range of drugs available for primary health workers to prescribe. Implementation has been slow, and we have yet to see the benefits of better drug supply, stock management and use. An amendment to the act aims to speed up the process by fast-tracking the registration of medicines on the essential drugs list.

A drug is often prescribed for reasons other than its effectiveness and price. The ministry hopes to discourage "perverse incentives" by putting a halt to free samples from manufacturers to licensed dispensers, and preventing suppliers from giving bonuses or rebates for medicines.

An amendment which irks manufacturers prohibits the sale of medicines to the state which bear the brand name of those drugs. The intention of the ministry is to make prescribing for practitioners as clear and simple as possible. Given the immense difficulties in providing continuing support and information updates to rural health workers, this proposal makes sense.

Taken together, the proposals in the Medicines and Related Substances Control Amendment Bill represent a logical approach. Proposals such as routine generic substitution are fundamental to cost containment and rational drug use, and should not be further diluted.

An area of doubt is parallel importation, where concerns about fake medicines are real, despite the obvious cost benefit of the proposal. Either stringent controls need to be put in place, or the ministry should use parallel importation as a bargaining chip to ensure other vital amendments to the act are retained.

☐ *David Harrison works for Health Systems Trust, a non-government organisation which supports health care reform. He writes in his personal capacity.*

Medicine reforms to go ahead despite legal threats, says Zuma

(96)

Jacob Dlamini

CAPE TOWN — The health department would go ahead with plans to reform the regulation of medicines despite the threat of legal action from the pharmaceutical industry's threat of legal action, Health Minister Nkosazana Zuma said yesterday.

While she would prefer that the dispute between the department and the industry did not go to court, she was confident the department would win.

She said any legal challenge would delay the introduction of the Medicines and Related Substances Control Amendment Bill, which is currently before the parliamentary health committee for debate.

Zuma said the bill was designed to increase access to primary health care and to redress historical inequities in the distribution of resources within the constraints of a limited budget.

The bill, which has drawn the ire of pharmaceutical companies and doctors, is intended to allow for the parallel importation of drugs into the country; fast-tracking the registration of certain drugs; ending the practice of "bonusing" by which practitioners are enticed to prescribe the products of particular companies; regulating the marketing practices of pharmaceutical companies and legalising the generic substitution of drugs.

Zuma said health department investigations had shown that SA was among the top five countries in drug pricing and that people were paying too much for medicine.

The department needed legislation to import drugs from foreign companies if their SA subsidiaries did not offer a reasonable and competitive price.

Zuma said the department would not source its entire essential drugs list internationally but would use parallel importing to make locally expensive drugs readily available.

The legalisation of generic substitution would allow pharmacists to prescribe cheaper drugs which were just as safe and would have the same effect.

The bill would require doctors to indicate in their own handwriting if they did not want substitution to take place, while pharmacists would have to inform patients of available substitutes.

Zuma said ending bonusing would not take away the right of companies to give out samples, but would ensure that "the moral hazard" which could affect clinical judgment was removed.

BD 16/5/97

was R250m, and additional offices would be purchased in Maritzburg and Durban to cut down on annual rent of R25m.

It was understood that the IFP was willing to scale down projects, provided the ANC agreed that they could go ahead.

The first phase of the project was for offices for premier Ben Ngubane and provincial director-general Otty Nxumalo. The ANC and IFP agreed that costs be slashed from about R70m to R40m, but this still needed to be approved by the legislature.

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Census costs extra R31m

Linda Ensor

BD 16/6/97

CAPE TOWN — The processing of millions of census forms had proved more expensive than initially anticipated but the additional costs should be fully covered by R31m in grants, Finance Minister Trevor Manuel said in Parliament yesterday.

Manuel opened the debate on the Central Statistical Service (CSS) which was incorporated under the finance department a few weeks ago. He said that as a result of a R20m grant from the reconstruction and development programme and R11m from the Swedish International Development Agency, the processing phase and the budget for the entire exercise was expected to break even.

"The overall cost will then be R398m — approximately R10 a head — which is about the same as Zimbabwe and less than half the figure of Australia."

The target date for the detailed results had been postponed from December to April next year, 16 months after the fieldwork. This was, by international standards, typical for a country of SA's size. But the CSS would produce a preliminary count, broken down by province, probably by the end of next month.

On the transformation of the CSS, he said consideration was being given to a system of user-pays for survey material. The user-pays principle would also soon be applied to economic series, which were of specific interest and would otherwise have to be abandoned, he said.

ZUMA TO CRACK DOWN ON 'BONUSING'

Freebies for doctors to end

CT 16/5/97 (96)

MANUFACTURERS' handing out of free drugs to doctors in the form of samples will be limited under a proposed new law. **MELANIE GOSLING** reports.

DOCTORS' "freebies" from drug companies will cease once the new bill on medicines becomes law.

Health Minister Dr Nkosazana Zuma's Medicines Control Amendment Bill aims to bring down the country's medicines bill and to keep drug-taking within a "rational" use.

Zuma said at a press conference yesterday that the practice of "bonusing" would be banned because it often interfered with the doctor's clinical judgment and enticed practitioners to prescribe more of a particular company's products.

"Bonusing often takes the form of cash payments or the offer of overseas holidays. The object is to entice the practitioner to use that particular drug, and not because it is the best drug for a specific ailment," Zuma said.

The bill also limits the handing out of free drugs in the form of samples.

"Very often excessive quantities of samples are given by drug companies, which leads to doctors and pharmacists selling them to their patients. Sampling will therefore be limited to the minimum quantities required to demonstrate the effective use of the product," she said.

The bill allows for parallel importing, which means that drugs from the same company may be imported to South Africa from another country, where they may be sold cheaper.

Said Zuma: "International pharmaceutical companies price their products differently on different markets and the prices in South Africa are among the highest in the world.

"Through parallel importation a product can be imported from another country where the same product, made by the same company, is available at a much lower price."

This has come under attack from the manufacturing industry, who say they have no objection to valid competition, but believe such importing is unfair.

Zuma says she is "appalled" that there should be so much opposition to parallel imports, which happens all over Europe.

Pharmaceutical Manufacturers Association of SA (PMA) chief executive Ms Mirryéna Deeb said: "She (Zuma) doesn't say the parallel imports will be subjected to registering or testing. There is nothing in the legislation that indicates there will be any form of record-keeping for these imports, so we'll have a whole unaccounted batch of medicines arriving in this country. But we have to register our drugs, which makes the importing unfair.

"It also opens the door to fakes or expired medicines. In the rest of Africa, up to 50% of medicines are fakes or have expired. Some drugs simply lose their efficacy after expiry, but others actually degenerate into dangerous substances, sometimes lethal, like some of the antibiotics," Deeb said.

In the bill, generic substitution will be legalised, and pharmacists will have to inform patients of the options available to them. If the patient refuses a generic drug, this has to be recorded in a register.

"There is no duty on the pharmacist to tell the consumer he can refuse the generic," said Deeb.

"And why should patients have the onerous burden of deciding what drug to take, and why should it be recorded in a register that the patient refused the generic? It sounds to us like a bit of a witch-hunt."

'APPALLED': Health Minister Nkosazana Zuma explains the new medicines bill. *PICTURE BENNY GOOL*

Medicine plans leave a bad taste

By Janine Sinon
Medical Correspondent

Health sources fear that Health Minister Nkosazana Zuma's proposed new medicines legislation will emasculate the Medicines Control Council.

This is the authoritative body charged with ensuring the safety and efficacy of medicines registered for local use.

The MCC also sets standards for ethical and scientific research. Its intervention in the Virodene Aids-drug controversy, clarifying where researchers had erred, and what clinical and scientific principles should be met to continue the work, is considered masterly.

The Medicines and Related Substances Control Amendment Bill is aimed at giving a legal framework to the National Drug Policy, which was released in January 1996 and aimed at securing a safe, cost-effective and accessible medicine supply.

MCC chairman Professor Peter Folb and vice-chairman Professor Peter Eagle met parliamentary portfolio committee on health chairman Dr Abe Nkomo yesterday, and the MCC will be making a full submission at the public committee hearings on the bill next week.

Folb declined to comment, saying the MCC was in discussion with the minister and the committee and that he did not want to jeopardise the talks.

Nkomo confirmed the meeting, but refused to disclose the details of the consultations.

However, it is understood the MCC's deep concerns centre on the fact that the draft bill gives the minister the power to overrule the council, the general lack of consultation and insight, loopholes on proposals for parallel importing (finding cheaper sources of drugs already registered and available in South Africa), and the fast-tracking of drugs on the essential drugs list.

Worry that minister could overrule council

The draft bill has also enraged the Pharmaceutical Manufacturers' Association, which says it infringes intellectual property rights.

PMA chief executive Mirryena Deeb said the PMA would take legal action and petition President Mandela for a ruling on whether that principle would be respected in South Africa; getting governments to accept intellectual property rights was regarded as the international pharmaceutical manufacturer's biggest single challenge.

Deeb said the legislation contained severe restraints on intellectual property rights. It would not allow firms to use brand names for government tender and, by legalising parallel imports, would violate the intellectual property rights of the firms which registered the drug in South Africa.

A source in a generic-drug company, which has recently entered the local market, said multinationals were fighting to protect profit margins which were significantly higher than elsewhere in the world.

In SA, drugs which had come off patent were sold at up to 40% above the cost of generics, the source said.

The bill is one of three to be heard by the committee next week, as the Health Department progresses with the 10 pieces of legislation it is expecting to pass this year to give legal framework to the shift in health policy over the past three years.

Also up for portfolio committee hearings next week are the Pharmacy Amendment Act, which allows for ownership of pharmacies to be opened to all, and the Medical, Dental and Supplementary Health Service Professions Amendment Bill.

This bill contains enabling legislation for the controversial two years' vocational training for doctors, continuing medical education, as well as community representation on the Medical and Dental Council and the registration of foreign doctors.

Parties reject Zuma's rush to pass bills

By Jovial Rantao
Political Correspondent

Cape Town – Five opposition parties have objected to attempts by Health Minister Dr Nkosazana Zuma to push through three pieces of legislation before the end of the current parliamentary session.

In a joint statement, the NP, the DP, the IFP, the FF and the PAC objected to an attempt to push the Medicines and Related Substances Control Bill, the Medical, Dental and Supplementary Health Service Professions Amendment Bill, and the Pharmacy Council Bill through Parliament.

The parties said that if adequate time was not provided, the bills would represent a mockery of the parliamentary process.

"These are major bills, with far-reaching implications for the sale of pharmaceuticals and the roles of the Medical and Dental Council and the Pharmaceutical Council. Aspects of the white paper have a bearing on them, and discussion of the white paper should be completed before they are entertained," the parties said in a joint statement.

Zuma's spokesman Vincent Hlongwane said the minister did not think there was any conflict in introducing the bills while the Health White Paper was being introduced.

Zuma takes on the drug companies

(96)

Minister determined that South Africans will play less for their medicine

Star 16/5/97

By Jovial Rantao
Cape Town

Health Minister Dr Nkosazana Zuma will go ahead with plans to introduce legislation that would significantly lower the price of drugs, despite opposition from pharmaceutical companies, which have threatened legal action.

Zuma said yesterday the legislation would also force dispensing doctors to be licensed and discourage pharmacists from dispensing for a profit.

At a press conference in Parliament, Zuma said she was confident the Department of Health would win any legal action brought by pharmaceutical companies unhappy with proposed amendments to the Medicines and Related Substances Control Act.

The amendments would allow for the parallel importation of drugs into the country.

"Through parallel importation, a product can be imported from a country where the same product, made by the same company, is available at a much lower price.

"This will be resorted to in order to make available those drugs which are much too expensive locally. There should therefore be no fear that this could lead to entire factories having to close up locally.

"The impact should not be different from that felt when a company loses a tender in a given year, and should certainly contribute to increasing competition," Zuma said.

She said discussions were held with stakeholders in the pharmaceutical industry after the release of the National Drug Policy Committee's report in 1994. Workshops were held in 1995 and bilateral meetings held with individual stakeholder groupings, and the process culminated in the drafting of the drug policy.

"The goal of the national drug policy is to ensure an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens and the rational use of drugs by prescribers, dispensers and consumers.

Reliable supply of affordable, safe drugs to all is aim

"Amendments to the Pharmacy Act and the Medicines and Related Substances Control Act are aimed at bringing the two in line with the national drug policy," she said.

Zuma said the proposed legislation also sought to prohibit dispensing doctors from receiving "bonuses" from pharmaceutical companies. Reports have suggested that most of South Africa's 6 000 dispensing doctors have received "bonuses" in the form of excessive samples of drugs, cash payments or offers of overseas holiday.

Zuma said the practice interfered with doctors' clinical judgment and led to more of a certain product being prescribed because it would be available in large quantities.

The advertising, promotional and marketing practices of companies would be regulated through the enforcement of an ethical code of marketing which required that all promotion-making claims concerning drugs should be reliable, accurate and up to date.

Zuma said generic substitution would be legalised. This would be permissible where a cheaper drug was supplied in the place of a more expensive generic equivalent.

On the licensing of dispensing doctors, Zuma warned that doctors whose primary aim was to dispense for profit were unlikely to be granted a licence.

"Pharmacies must dispense for a professional fee and not for a profit markup. They're professionals and should not be making money from drugs and medicines but from their professional service. We're removing the incentive for dispensing expensive drugs," she said.

The NP, DP, IFP, FF and PAC objected to the attempt to push the Medicines and Related Substances Control Bill, the Medicine, Dental and Supplementary Health Service Profession Amendment Bill and the Pharmacy Council Bill through Parliament.

Zuma pledges safe drugs

(96)

JENNY VIALL
HEALTH REPORTER

ARG 16/5/97

Proposed changes to the law to reduce the high cost of medicines in the public and private sectors will not compromise safety and effectiveness, says Health Minister Nkosazana Zuma.

Dr Zuma said a legal challenge from pharmaceutical companies to the Medicines and Related Substances Control Bill would delay its implementation, but she was confident of winning the case.

"What we're trying to do is reasonable, and international practice."

Medicines in South Africa were among the most expensive in the world, ranking in the top five, and accounted for 30 percent of medical costs in the private sector. More than R2-billion, or 11 percent, of South Africa's health budget was spent on medicines, she said.

She was appalled there was so much opposition to parallel importing, which allowed drugs to be imported from a company's factory in another country if prices were cheaper there.

But this did not mean that all drugs would be imported, said Dr Zuma.

"This depends on whether companies give us a reasonable and competitive price," she said.

Dr Zuma said it would be irresponsible of her not to take measures to contain or lower the costs of medicines in South Africa.

The issue of dispensing doctors will be dealt with in the Pharmacy Bill.

·aw could negate pharmaceutical proposals, say lawyers

(96) BD 19/5/97

·ryn Strachan

intellectual property laws
l be used to stop Health
ster Nkosazana Zuma's
· to allow the parallel im-
·tion of pharmaceuticals,
.rs said yesterday.

·earings on Zuma's propos-
hich have been introduced
rliament, will be conduct-
the parliamentary health
)lio committee this week.

e proposal of parallel im-
·ion has raised the ire of
·armaceutical industry. If
·ed, it would mean even if a
·ular drug is manufac-
in SA, the state would be allowed to buy the same drug from another country if it could be obtained at a lower price.

The health ministry has said this proposal is key to containing the spiralling price of medicines in SA.

However, John & Kernick law partner Llewellyn Parker said "while amendments to existing medicines control legislation may enable the parallel importation of branded pharmaceuticals at lower prices than those available in SA, our intellectual property laws, if applied correctly, would negate these amendments".

Zuma's proposals would also be in contravention of the international Agreement on Trade Related Aspects of Intellectual Property Rights, he said.

Sapa reports the Pharmeceutical Manufacturers' Association of SA (PMA) said at the weekend the proposed Medicines and Related Substances Act had the right goal, but would seriously disadvantage patients.

"The PMA supports Zuma's goal of ensuring an adequate and reliable supply of safe, cost-effective, quality drugs to all South Africans. It is, however, concerned that a number of proposals before Parliament in draft legislation would do little to help her realise these objectives but would instead harm the industry irreparably and endanger consumer safety," PMA CE Mirryena Deeb said.

The PMA represents 90% of local and international manufacturers in SA.

Deeb said the association was concerned Zuma's "fast-track" registration method paved the way for unequal registration requirements, particularly for imported drugs.

The process was approved last year by the Medicines Control Council, but the health department had consistently refused to divulge the procedures and criteria allowing an applicant to make use of the "fast-track" method.

The proposed act did little to clarify this, Deeb said.

While the PMA welcomed international competition and respected Zuma's right to tender internationally, the consequences of fast-tracking for consumers could be grave.

"All medicine used in SA must be subject to the same safety and efficiency standards if the public is to be protected from harmful substances."

The PMA also opposed Zuma's planned "parallel imports". While it was true that currency fluctuations and differing levels of government control and subsidies could mean "parallel imports" were cheaper, it was not likely this practice would ensure a constant supply of reliable medicine.

Deeb said that parallel importation was notorious for easing the entry of established markets by counterfeit, fake, expired and harmful medicines and up to 50% of medicines found in Africa were fake because of this practice. The practice would also ignore several SA trademark laws and disturb the chain of accountability.

A number of European governments were seeking to outlaw the practice because of the trouble they had experienced. Zuma's proposal that generic substitution be made mandatory was also cause for concern, Deeb said.

The proposed act demands that pharmacists substitute generics for prescription medicine on all prescriptions, but does not make it clear that the patient is under no obligation to accept the generics.

Patients who refuse the generic substitution must have this recorded in a register, an infringement of the patient's right to choose, Deeb said.

Zuma's draft legislation also included proposals to end bonusing, sampling and price discounting.

Bonusing, the practice of giving free goods to buyers instead of cash discounts, was a normal business practice used legitimately by competitors in all commercial spheres. Sampling was important in medicine to try out innovations.

Zuma's proposal to regulate advertising, promotional and market practices was unnecessary because the industry's stringent code of ethics was self-regulatory, she said.

Pharmaceutical body against cheap drug move

By Trove Lund

Consumer safety will be put in "grave danger" if Parliament accepts the proposed new medical legislation now before it, the Pharmaceutical Manufacturers' Association of South Africa (PMA) has warned.

The objections follow Health Minister Nkosazana Zuma's proposed legislation that would allow cheaper drugs to be imported.

It would also compel every pharmacist to substitute every prescription with cheaper generic drugs; regulate all of the pharmaceutical industry's advertising, promotional and marketing practices; and establish a dual system for drug legislation.

Although it supports the Government's goal of an adequate, safe and cost-effective supply of drugs for South Africa, the PMA said the consequences of the legislation could be "grave".

Zuma could not be reached for comment yesterday.

(96) Star 19/5/97

Council objects to drugs bill

BD 21/5/97 (96)

Jacob Dlamini

CAPE TOWN — A health bill currently before parliament would weaken the control of drugs, the Medicines Control Council told the parliamentary health committee yesterday.

Council clinical committee chairman Amtoine van Gelder said the Medicines and Related Substances Control Amendment Bill would have an adverse effect on drug regulation.

The bill was ambiguous, which could lead to multiple interpretations, and contained deficiencies which could expose council members to legal action.

The bill forms part of the national drug policy, launched last year to ensure an adequate and reliable supply of safe and cost-effective drugs.

It calls for the parallel importing of drugs if the manufacturer's SA subsidiary proves too expensive, the speedier registration of drugs, as well as allowing for generic substitutes to reduce costs. It also seeks to end bonusing, a practice by which doctors are enticed to prescribe the products of certain companies.

Van Gelder said the amendments would compromise public confidence in the safety of available medicines.

Council vice-chairman Peter Eagles said some of the proposed amendments were in contrast to the national drug policy and would weaken the council's ability to evaluate the safety, efficacy and quality of medicines.

Eagles said parallel importing would allow for drugs to be brought into the country without having to go through the registration system.

The requirement that products supplied to the state should not bear brand names was a violation of intellectual property rights. In terms of the new bill, the council would be required to carry out extra duties without adding value to the medicine control process.

Eagles said the amendments would curtail the council's autonomy and turn it into a "juristic person", exposing it to legal challenges from the public and the pharmaceutical industry.

National Party spokesman Willem Odendaal accused Health Minister Nkosazana Zuma of trying to grab control over health care in a dubious way.

Inkatha Freedom Party spokesman Ruth Rabinowitz said the bill gave Zuma excessive powers and reflected a lack of faith in the private sector.

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Pharmacy bill concerns will be thrashed out

(96)

Jacob Dlamini

BD 22/5/97

CAPE TOWN — The health department is to meet the Interim Pharmacy Council in a bid to thrash out differences on a controversial bill which would allow supermarkets and laymen to trade in prescription medicines.

The meeting is expected to take place within weeks and will focus on clauses in the Pharmacy Amendment Bill, currently before Parliament.

The bill, designed to improve access to medicines and pharmaceutical services, calls for the deregulation of existing laws to allow people other than trained pharmacists to own pharmacies.

Parliamentary health committee chairman Abe Nkomo called for the two parties to meet after the council expressed concerns about the bill yesterday.

Council legal advisor Pierre Marais said it was badly worded, would create moral hazards and offer perverse incentives which could be exploited.

Marais said the bill would discriminate against pharmacists who had to have a licence for themselves and their premises before they could operate.

It would allow prospective pharmacy owners to apply only for a licence for their premises as the bill would give everyone an automatic right to trade.

Marais said the bill would also make it impossible for the department to stop people from owning pharmacies, including pharmacists who had been struck off the roll for unprofessional behaviour.

Marais said the bill failed to make provision for the appropriate monitoring of nonpharmacists owning pharmacists and would result in the unequal treatment of various health personnel before the law.

He said a complete transformation of existing disciplinary measures was needed to bring them in line with peer review and public accountability.

Marais said provincial health authorities lacked the capacity to take responsibility for inspection of private health facilities and licensing of people wishing to operate pharmacies, as the new bill proposed.

How the retail pricing system affects your pocket

The antidepressant Prozac, manufactured by Eli Lilly, is one example of how retail drug-pricing and medical-aid-reimbursement systems work in South Africa.

According to pharmacy clearing house Mediscor, the current "blue book" or retail price for a pack of 28 20mg capsules is R306,77.

That's the price you'll pay if you are not on a medical aid, if your pharmacy doesn't give a discount for cash or if you don't ask for a generic substitute.

From next week, you can also ask to pay the new professional-fee-based price of the Pharmaceutical Society of SA, which works out to about R262.

Prozac's generic equivalents, Lorien, made by SA Druggists, and Lilly Fluoxetine, made by Eli Lilly, retail at blue-book prices of R125,86 and R182,69 respectively. The PSSA professional fee price is R121 and R168.

Most medical aids reimburse at the maximum medical aid price – a guide for generic substitution drawn up by pharmacy clearing house Medikredit.

They are also still deciding whether to accept the PSSA professional fee structure, or that of the Representative Association of Medical Aids. – Medical Correspondent.

Controversy over drug-pricing policy

(96) Star 23/5/97

Health Ministry and Medicines Control Council in bid to thrash out problems over bill

By Janine Simon
Medical Correspondent

Consumers are no closer to having the legal right to be informed of cheaper generic substitutes for prescription drugs.

They now face further confusion over drug prices as pharmacists introduce a professional-fee-based drug-pricing system.

The professional-fee-based price system will be phased in as from next week.

The Health Ministry and the Medicines Control Council met in Cape Town yesterday to discuss conflicts on the Medicines and Related Substances Control Amendment Bill.

The bill was drafted to give a legal framework to the National Drugs Policy released in January 1996.

It proposes to make generic substitution a legal option, license dispensing doctors, allow parallel drug imports, and ban drug-company bonuses to doctors, but has drawn fire for giving the minister excessive powers and emasculating the Medicines Control Council.

Pharmacists are, meanwhile, preparing to give effect to another aspect of the National Drug Policy. Professional fee-based pricing for prescription drugs is an attempt to help lever the private sector out of years of hyperinflation of medicines prices.

For at least the next month, pharmacists will be running a dual pricing system, said Willie Kriel, head of the professional department of the Pharmaceutical Society of South Africa (PSSA).

This was because pharmacists still had contractual agreements with medical aids based on previous systems, he said.

From Monday, anyone who pays cash upfront for prescription drugs at pharmacies and members of the few medical aids which have agreed to the PSSA's version of the new system – such as Southern Healthcare and Sanmed – can be charged the professional fee-based price.

This is the wholesale price, plus 5% finance charges, R3 for practice expenses and a professional fee of R15 for every prescription drug dispensed, excluding VAT, said Kriel.

The PSSA system will see the cost of top-range drugs plummet, including the price of some generics, but will add a small rand value to the cost of less pricey drugs.

For example: 15 500mg of the antibiotic Amoxil will drop from R70,22 to R65,89; the anti-ulcer drug Tagamet will drop from R403,47 to R285,89 for 60 400mg tablets, and its generic anti-ulcer Adco-Cimetidine from R253,90 to R187,11. But the painkiller Stopayne will increase from R41,95 to R47,22, and its generic Stilpayne from R20,52 to R33,08.

In some cases the final retail price is now higher than that which consumers were paying when they were given cash discounts off the old "blue book" recommended retail prices.

Medical aids not yet contracted to the PSSA's new system will have to choose whether they use the PSSA, or the system suggested by the Representative Association of Medical Schemes (Rams), said Kriel.

Most medical aids will only reimburse members for the cost of generic equivalents to prescription drugs, the so-called maximum medical aid price (MMAP) set by the four clearing houses which process pharmacy claims for medical aids.

Rams' recommended medicines scale of benefits is the wholesale price as of April 1997 (where available) plus a R19 per line dispensing fee, to a maximum of three items per script. It is significantly lower than current blue-book prices, said policy director Dr Aslam Dasoo.

But medical aids must still apply the Rams figures to their own MMAP prices, and decide how they wish to reimburse.

"It is up to members to demand explanations from their medical aids," Dasoo said.

Confusing Changes To Medicine Prices

Classification		Example	'Blue Book' price	'New PSSA Professional based-price'	Difference
Anti-arthritic	Original	Indocid R® x 30	R245,61	R181,63	– R63,98
	Generic	Articulen LA® x 30	R112,61	R93,86	– R18,75
Anti-ulcer	Original	Tagamet® 400mg x 60	R403,47	R285,89	– R117,58
	Generic	Adco-Cimetidine® 400 mg x 60	R253,90	R187,11	– R66,79
Antibiotic	Original	Amoxil® 500mg x 15	R70,22	R65,89	– R4,33
	Generic	Adco-Amoxycillin® 500mg (15)	R42,34	R47,78	+ R5,14
Painkiller	Original	Stopayne®	R41,95	R47,22	+ R5,27
	Generic	Stilpane®	R20,52	R33,08	+ R12,56
Antihypertensive	Original	Tenormin® 100 x 30	R162,14	R126,55	– R35,59
	Generic	Ten-Bloka® 100 x 30	R83,16	R74,42	– R8,74
Diuretic	Original	Moduretic® x 30	R99,07	R84,93	– R14,14
	Generic	Adco-Retic® x 30	R22,23	R34,14	+ R11,91

(3) whether any of these officials have been replaced; if not, what is the position in this regard; if so, what are the relevant details in each case? N1042E

The MINISTER OF HOME AFFAIRS:

(1) Yes.

(a) 4 officers

(b) and (c)

Position	*Years Experience*
Regional Director	29 years
Deputy Director	27 years
Assistant Director	28 years
Senior Administrative Officer	32 years

(2) Severance packages were granted to the officers concerned on their written request.

(3) None of these officers have been replaced, since the Department is still awaiting a decision from the Department of Public Service and Administration regarding the filling of vacancies caused by severance packages in the Department. It is, however, being endeavoured to fill the post of Regional Director as soon as possible.

INTERPELLATIONS

The sign * indicates a translation. The sign †, used subsequently in the same interpellation, indicates the original language.

(96)

Parallel importation of medicines

1. Mr M M CHIKANE asked the Minister of Health:

(1) Whether she will make a statement on the parallel importation of medicines, with specific reference to who is allowed to do so and what the reasons are for the parallel importation of medicines;

(2) whether any drugs are currently being so imported; if not, what is the position in this regard; if so, which drugs? N1263E.INT

The MINISTER OF HEALTH: Madam Speaker, I am not sure whether this interpellation is to be debated or not. Can we ask the person who put it on the Question Paper? I am under the impression that it might have been withdrawn.

Mr M M CHIKANE: Madam Speaker, I would like to withdraw the interpellation, but would like it to be debated at a later date.

The DEPUTY SPEAKER: Order! Interpellation No 1 will be withdrawn.

Mr M J ELLIS: Madam Speaker, this is absolutely unacceptable. [Interjections.] I cannot believe that we can, at this stage, have an interpellation withdrawn. I am due to speak. I have two minutes in this interpellation. I have prepared myself, and it is a matter which I feel is of great importance. Yet at the beginning of this sitting we are informed that this interpellation has been withdrawn. This is absolutely unacceptable. [Interjections.]

The DEPUTY SPEAKER: Order! Hon member, can we make an appeal to you that perhaps the issue . . . Hon Doidge, did you want to shed some light on this matter?

Mr G Q DOIDGE: Madam Speaker, on a point of order: Comrade Moss Chikane is the interpellant, and not Mr Mike Ellis, and he has the right to withdraw if he so wishes.

Mr M J ELLIS: Madam Speaker, I accept the right of anybody to withdraw any question or interpellation. But surely the governing party should have the manners, the decency, to inform everybody concerned well in advance. I stress the point that this is absolutely unacceptable. [Interjections.]

Mr G Q DOIDGE: Madam Speaker, we do apologise to the hon Mike Ellis.

The DEPUTY SPEAKER: Order! Hon Ellis, we hope that you accept the apology. May I just say that when there is a situation of this sort, we appeal to the Whips please to try to communicate with one another in such a manner as to smooth things out.

Mr M J ELLIS: Madam Speaker, I have respect for Mr Doidge. He is a good man. Since he has asked for acceptance of his apology, I will accept it.

1. Mr M M CHIKANE – Health. [Withdrawn.]

Problems with building of houses/housing subsidies

2. Mr J A RABIE asked the Minister of Housing:*

Whether, with reference to the termination of the contract of the Director-General of her Department, any problems are experienced countrywide in respect of the (a) building of houses and/or (b) utilisation of housing subsidies; if not, what is the position in this regard; if so, what are the biggest problems? N1312E.INT

The MINISTER OF HOUSING: Madam Speaker, my response to the hon Mr Rabie's question is that no problems are being experienced countrywide in respect of the building of houses. As I announced on 6 May, we have passed the halfway milestone in our housing subsidy programme. We now have more than 880 000 subsidies already released, and almost 200 000 houses have already been built or are under construction. The major beneficiaries of these subsidies are people who earn R800 per month or less or people who are unemployed.

Our delivery is improving, because we are focusing on removing obstacles impeding delivery. We have implemented recommendations made in the first and second task team reports. We have established housing institutions to assist in speeding up access

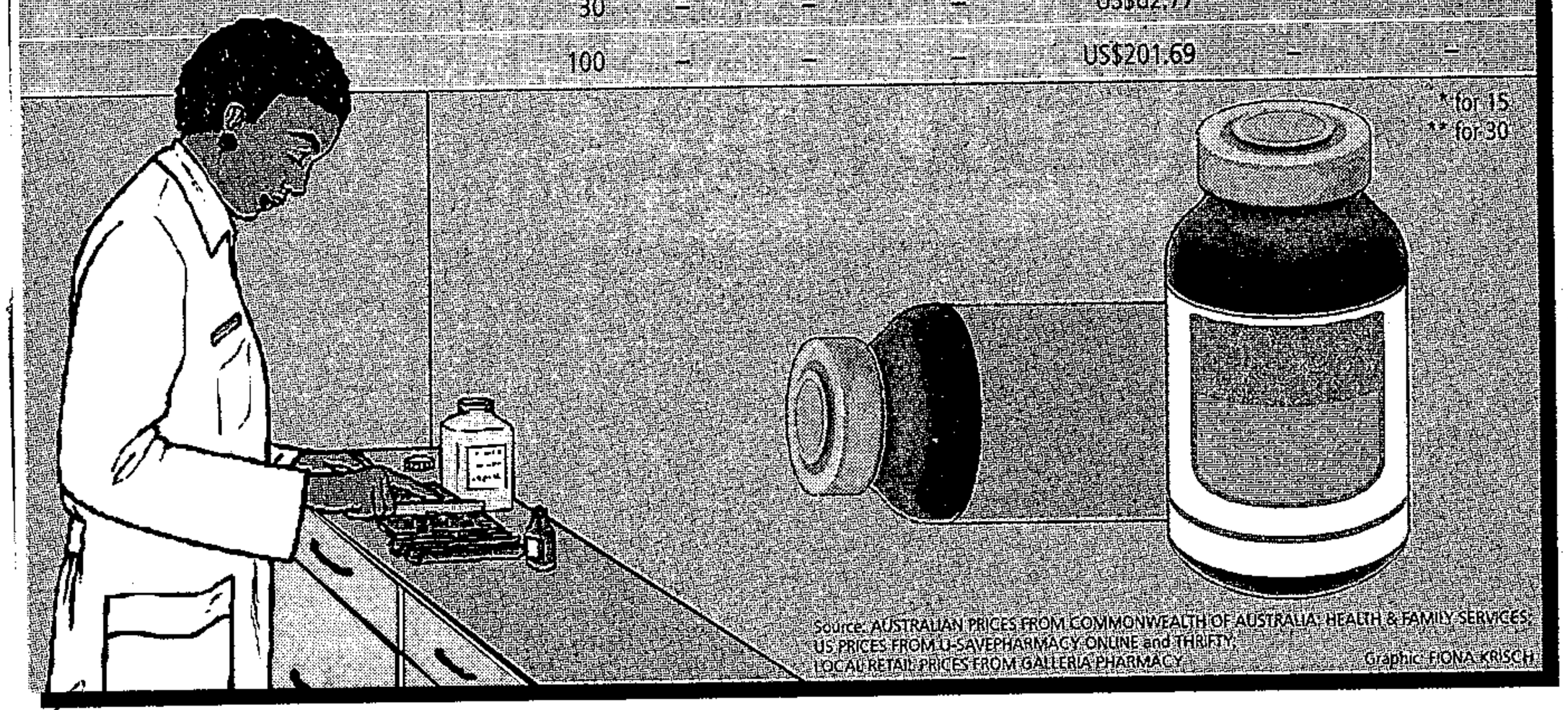
Supplement C

HEALTH CARE

Sunday Times Business Times
May 25 1997

BRANDED NAME PRESCRIPTION DRUGS' PRICE COMPARISONS

TRADE NAME	GENERIC NAME	STRENGTH	PACK SIZE	TENDER PRICE TO SA GOVT	"RETAIL" PRICE	DISCOUNT AT GALLERIA PHARMACY	US RETAIL PRICE TO CONSUMERS	AUSTRALIAN GOVT PRICE	PRIVATE PRICE
Zocor	Simvastatin	10mg	28	R62.85	R257.16	R167.15	US$67.69	**$A42.01	**$A66.41
		20mg	28	R123.02	R389.34	R253.07	US$104.69	**$A58.07	**$A91.96
Augmentin	Claunlank Acid	375mg	100	R197.22	R631.55	R442.08	–	*$A13.62	*$A21.87
Renitek	Enalapral	5mg	28	R7.65	R91.19	–	–	**$A21.00	$A32.98
		5mg	100	–	–	R59.27	US$85.93	–	–
Roaccutane	Isotetinoin	10mg	60	–	R555.73	R361.22	US$251.00	$A101.06	$A160.35
Voltaren	Diclofrenac Sodium	25mg	100	R3.25	R87.01	R60.91	US$74.00	$A14.49	$A22.62
Prozac	Fluoxetine	20mg	28	–	R306.77	R199.40	–	$A35.50	$A56.05
			30	–	–	–	US$62.77	–	–
			100	–	–	–	US$201.69	–	–



Source: AUSTRALIAN PRICES FROM COMMONWEALTH OF AUSTRALIA: HEALTH & FAMILY SERVICES; US PRICES FROM U-SAVEPHARMACY ONLINE and THRIFTY; LOCAL RETAIL PRICES FROM GALLERIA PHARMACY

Graphic: FIONA KRISCH

Discrepancies exist in medicine prices

(96) ST(BT) 25/5/97

THIS table shows six of the top 10 selling branded prescription drugs in South Africa. The South African prices reflect the tender price — at which the drug company sold the product to the state — the "retail price" which several retail outlets still charge and the type of discount prices available to those prepared to scout around.

The United States prices reflect those an ordinary consumer would pay for the same drug in Los Angeles. But US consumers largely buy generic substitutes when they are available, almost all of which are very much cheaper.

Almost 50% of US citizens belong to managed care-type insurance companies who demand either that the generic drugs are bought in bulk by mail order, or insist that the generic alternative be supplied. They seldom pay for a branded prescription drug when a generic is available.

The pharmacist who supplied some of the US prices thought the inquiry would be better directed to Mexico where even the branded drugs, he said, were 80% cheaper than in LA.

The Australian prices reflect the peculiarities of that country's government subsidy system. The private price is an estimate of what a consumer would pay in a pharmacy with a prescription, but without the government subsidy scheme. The "government price" is the amount a pharmacist would receive for dispensing the drug to a patient. But the amount a patient pays (aside from the private price) depends on the category of patient and therefore the subsidy. Pensioners and other low-income earners, for instance, never pay more than $A3,20. And no Australian has to pay more than $A20,00.

The retail prices of drugs in each country will show the characteristics of the distribution system as well as government systems.

South Africans can see that a huge discrepancy exists between the prices pharmaceutical companies sell to the state on tender and the amounts they recoup from private patients.

Council squares up to fight Zuma's Bills

(96)

ST (BR) 25/5/97

PHARMACEUTICAL INDUSTRY

By PAT SIDLEY

THE Medicines Control Council has joined the throng of stakeholders to object to the Health Department's package of Bills aimed at changing the way pharmaceuticals reach the market.

According to one multinational pharmaceutical company, the council is prepared to go to court to assert its rights. The Medicines Control Council is the body which regulates the standards, quality, safety and efficacy of drugs that reach consumers.

Pharmaceutical companies have objected to almost all the changes proposed by Health Minister Nkosazana Zuma, which are aimed largely at bringing prices down and introducing more equity in the drugs market.

The council says the Bill "contains serious and fundamental flaws which, if not corrected, will immeasurably weaken the medicine control process in a retrogressive manner".

Chief among its problems is the fact that the proposed importation of medicines (through parallel imports or international tendering) will take place "outside the registration system", according to the council. The proposed system of registration will mean that imported drugs will not have to undergo the same rigorous inquiries as do those which are sold within South Africa, before they can register and reach the market.

The council has also objected to the process proposed in the legislation for appointing councillors, which, it believes, will seriously erode its present autonomy and allow the minister to override objections the council may have to a particular drug.

The council emphasised that "autonomy in this context means the fearless application of the discretion that the council has in the manner that it evaluates and interprets the safety, efficacy and quality of medicines". However, it also says it does not believe the council is not accountable to the public and to the minister for its operations.

The council believes a change of wording in the law will mean that whereas in the past the MCC and the minister had to reach consensus before regulations were made or action taken, the minister will, if the Bill becomes law, only have to "consult" the MCC and then do what she wants anyway. The council would become a legal entity in a different way from the way in which it is presently constituted. Because of the threat of litigation, the council has to function to the best of its capacity, and this could be impaired by the changes.

Regulatory authorities had their watchdog powers beefed up almost 30 years ago after the Thalidomide scandal to ensure that drugs which caused huge problems for consumers, could no longer reach the market. In most countries, since AIDS, methods have been devised to hasten certain drugs' passage onto the market — but in those countries efforts are made to ensure that quality is not compromised.

In many such countries, moves are afoot to try to force regulatory authorities to be less secretive. Although they all purport to work on behalf of the public, their work is regarded as the property of the pharmaceutical companies, and it is almost never disclosed to the public.

US pharmaceutical firms freeze investment

(96) BD 28/5/97

Linda Ensor

CAPE TOWN — US pharmaceutical companies have frozen new investments in SA pending the outcome of Health Minister Nkosazana Zuma's legislation on generic medicines.

US Congressman Robert Menandez said in an interview yesterday the proposed legislation violated the trademark rights of the US firms and they could file their objections with the World Trade Organisation as it was in contravention of WTO regulations.

The firms had raised their objections with the US government. Menandez said it was possible for the US government to raise objections with the SA government as it did with China over the violation of intellectual property rights.

Kathryn Strachan reports that the Pharmaceutical Manufacturers' Association said the US-based companies held the largest share of SA's pharmaceutical market with invest-

Continued on Page 2

Pharmaceuticals

(96) BD 28/5/97

Continued from Page 1

ments worth about $100m. These included Eli Lilly, Smithkline Beecham, Johnson & Johnson, Pfizer, Bristol Myers Squibb, Upjohn and Wyeth.

Merck, which had recently invested R500m in SA, was particularly angered by Zuma's proposals, the association spokesman said.

Menandez said US firms had no problem competing in the generic drug arena, but mandating the use of generic drugs infringed on their trademarks and undermined the free market.

"The firms say to me that they have tried to have input with the health ministry without much success. What is alarming to me is that if this goes ahead their investments will cease," he told a joint sitting of the finance and trade and industry committees.

He was one of a group of congressmen who briefed parliamentary committees on proposed US legislation — the African Growth and Opportunity Act — to promote trade and investment with sub-Saharan Africa.

□ A briefing on US relations with SA to Parliament's foreign affairs committee by the congressmen was held behind closed doors at the insistence of the Americans. SA foreign affairs officials said they could not understand why the US delegation required secrecy.

See Page 6

Pharmacy policy changes welcomed

BD 28/5/97 (96)

THE Hospital Association of SA (Hasa) has welcomed changes to the Pharmacy Act regarding ownership, saying the policy had been severely restrictive and made it impossible for private hospitals to render a proper pharmaceutical service.

Hasa executive director Dr Anette van der Merwe said her association supported strongly the proposal that applications be made to the director-general and not to the Pharmacy Council.

Van der Merwe, reacting to the pharmacy bill, said the director-general had no vested interest in the matter, and there was therefore no potential conflict of interest. "Applications will therefore be considered on merit, with the interest of the patient as the main objective," said Van der Merwe, whose organisation represents 97% of private hospitals in SA.

"With the move away from profit on drugs at retail level, to a professional remuneration for pharmacists, the profit making incentive is removed for corporations and body corporates not directly involved in the delivery of health care to apply.

"Pharmacists will in future be compensated for their professional expertise and the standard of service maintained."

The association said it was inappropriate for the Pharmacy Council to maintain and enhance the interests of the pharmaceutical profession.

"Instead, this role should be carried out by the professional organisation of the pharmaceutical profession which does not enjoy the statutory status of a professional body," Van der Merwe said.

The association warned therewould be a potential conflict of interests between members of the public and the pharmaceutical profession, should the pharmacy bill "hope to fulfil this dual role".

The National Assembly health committee is scheduled to hold public hearings on the draft bill on June 9. — Sapa.

Nurses face ban on giving drugs

(96) ARG 28/5/97

Durban – Nurses will not be able to administer or dispense drugs at ward level if a medicines bill is passed in Parliament – a move that health workers fear will seriously hinder hospital services and their ability to deal with emergencies.

The Hospital Association of South Africa (Hasa) warned that the proposed Medicines and Related Substances Control Amendment Bill could have dire consequences for patients.

Hasa's Anette van der Merwe said that according to the bill, nurses would no longer be able to administer six particular medicines nor would they be able to dispense drugs. She said the bill implied that at least 20 000 nurses would have to apply for licences and complete a supplementary course before they would be able to administer these drugs. – Argus Correspondent

Drug Bill provokes strong opposition

Sowetan 28/5/97 (96)

THE National Association of Pharmaceutical Manufacturers yesterday expressed its opposition to what it termed the "nationalisation" of the pharmaceutical industry in terms of the Medicines and Related Substances Control Amendment Bill.

NAPM executive director Barney Sachs said the Bill was not in the best interests of pharmaceutical manufacturers, gave Health Minister Nkosazana Zuma increased control over drug prices and would weaken the industry.

The Hospital Association of South Africa on Monday also warned against the proposed fast-tracking of the registration of essential drugs, envisaged in the Bill, as this could lead international companies to dump inferior drugs on South African markets.

"We are opposed to fast tracking – whereby drugs on the essential drug list would be approved in a shorter space of time," said Dr Annette van der Merwe, executive director of Hasa, which represents private hospitals.

"Using a different set of safety requirements for these drugs will reinforce the perception of a dual system for health care delivery between the public and private sector, with standards in the public sector inferior to those in the private sector," she said.

Van der Merwe also questioned the clause in the Bill which prevented nurses from administering schedule zero to six drugs which did not appear on a list prescribed by the minister.

This should not apply to all nurses as the proposal was made with primary health care – working without supervision – in mind, she said.

"The proposed Bill does not distinguish clearly between administering and dispensing drugs. Apart from the problems in terms of the administering of drugs, nurses would no longer be able to dispense drugs. This would hinder hospitals from providing an efficient 24-hour service and dealing with emergency cases," van der Merwe said. – *Sapa.*

THE BIG STORY

Is she dispensing the right medicine?

... and will South Africa's medical fraternity open wide to take it?

ARG 30/5/97 (96)

CHANGES TO LAWS GOVERNING MEDICINES ARE INTENDED TO ENSURE THAT PEOPLE HAVE EASY ACCESS TO GOOD QUALITY, AFFORDABLE MEDICINES, REPORTS JENNY VIALL. HOWEVER, THERE IS CONSIDERABLE OPPOSITION TO SOME OF THE WAYS IN WHICH THE HEALTH DEPARTMENT PROPOSES TO DO THIS

Three bills being debated in parliamentary committees will change the face of medicine supply in South Africa, directly affecting where we buy medicines and what they cost.

Among others changes, scheduled medicines will be available from your local supermarket, but it will become more difficult for your doctor to dispense medicines unless he or she works a certain distance from a pharmacy.

Your pharmacist will now be required by law to give you the option of a generic medicine at a cheaper cost and will no longer profit by selling more expensive medicines.

These and other changes, introduced in amendments to laws governing medicines and their control, will bring drug legislation in line with the health department's National Drug Policy and expedite the transformation of the country's health system.

Last week, Parliament's Portfolio Committee on Health, chaired by Abe Nkomo, heard submissions from health department officials and the three councils directly affected by the changes to legislation, the Medicines Control Council, the Interim Medical and Dental Council and the Pharmacy Council.

The changes have far-reaching implications for the way medicines are bought, sold and dispensed.

The bills affect a wide range of people, from private doctors who say it's their right to dispense medicines, to pharmacists, who will no longer profit from selling medicines, and the public, which uses health services both public and private.

One of the bills makes provision for the contentious issue of a vocational training programme for doctors and dentists.

The first set of hearings has highlighted the many areas of dissension between the Department of Health and the affected roleplayers.

It is now up to the committee to go through the bills, clause by clause, bearing in mind the many and complex objections to changes and make the necessary adjustments.

Public hearings on the bills are taking place.

All submissions so far agree that medicine prices must come down and all support the National Drug Policy.

Medicines in South Africa account for 30 percent of medical spending in the private sector, which means that we're spending far too much on prescripti on drugs.

The Department of Health spends more than R2-billion, or 11 percent, of its health budget on medicines.

Health Minister Nkosazana Zuma says that changes to legislation will bring down the prices of medicines in both sectors without compromising on safety and effectiveness.

"What we're trying to do is reasonable and international practice," she has said.

The three bills under discussion are the Pharmacy Amendment Bill, the Medicines and Related Substances Control Bill and the Medical, Dental and Supplementary Health Service Professions Amendment Bill.

One of the most controversial issues in the bills is that of dispensing doctors.

Dr Zuma has emphasised that her department is not banning dispensing, but regulating it in the interests of lower prices and better dispensing practice.

"We are saying doctors should be licensed to dispense. The primary reason should be a need to dispense, not to make a profit."

New requirements are that any doctor who wants to dispense must apply for a licence, which will be issued by the director-general of health in consultation with provincial health authorities according to the need for pharmaceutical services in that area.

It also requires doctors to do a course on dispensing, to be run by the Pharmacy Council, a provision to which the Interim Medical and Dental Council (IMDC) has objected.

The health department says it's a trend in many countries to break the link between dispensing and prescribing to remove the "perverse incentive" whereby doctors make money through their professional fee and also by selling medicines.

It's the professional duty of the pharmacy to dispense, the doctor to prescribe, it argues.

Dispensing doctors disagree, questioning the department's reasons for limiting dispensing. The IMDC says it is unacceptable that the director-general should now regulate dispensing doctors, which has been its duty until now.

Regulations already exist to control dispensing and discipline those who step out of line, says the council.

Changes to the law will remove the profit motive from dispensing, both for pharmacists and doctors.

This will be done by setting one "exit price" for medicines, which means that the doctor and pharmacist get paid a set fee (still to be determined) for each script they dispense, and not for the amount of drugs dispensed or what they cost.

With the profit motive removed, there is no longer a "perverse incentive", say doctors, so why is the department wanting to limit the number of dispensing doctors?

The health department is not about to back down, however. In her submission to the committee, Director-General of Health Olive Shisana said her department was "pitching this clause with as much passion as those opposing it".

"Our interest is to protect the public, theirs is to make money. There is likely to be little agreement between medical practitioners and ourselves," she said.

This was firmly rebutted by IMDC president Soromini Kallichrum, who said the council's priority was to protect the health of the public.

For the first time, the new law will bind the State to follow its own dispensing regulations, which include safe packaging and labelling. This might take some time, warned Bada Pharasi, a director in the health department, because there were many areas in the public sector where standards had to be brought up to scratch.

Standing firm: Minister of Health Dr Nkosazana Zuma is convinced she's doing the right thing

Vocational training, which means an extra two years' training for doctors, will come into effect from January next year in spite of vigorous opposition from junior doctors. The Government has given its assurance that there are enough posts available. A year's vocational service for dentists will be introduced in 1999.

'There is likely to be little agreement between medical practitioners and ourselves' – Olive Shisana

Other changes to the laws aimed at bringing medicine prices down are the outlawing of "bonusing" and sampling, which are seen as "perverse incentives" which can interfere with doctors' professional judgments.

Bonusing is the practice whereby pharmaceutical companies give doctors cash payments or overseas holidays as an incentive to prescribe that company's medicines.

Sampling is where doctors are given large quantities of samples which they sell or give away. There has, not surprisingly, been very little objection to these clauses.

Substituting generic drugs for brand name drugs has caused concern, however.

The bill makes it compulsory for pharmacists to inform people of the benefits of a generic drug (a drug with the same active ingredient as a branded drug, but cheaper) and substitute it with a generic medicine unless forbidden by the patient or the doctor to do so.

In South Africa, only 16 percent of drugs used are generics, compared to 40 percent in the United States.

Concern at quality and efficacy have been expressed, but generics will be no different from other medicines which have to be registered with the Medicines Control Council (MCC).

Another measure to bring drug prices down is the introduction of parallel importing, which allows the Government to import drugs from the same pharmaceutical company in another country if prices are cheaper there.

This does not mean that all drugs will be imported, Dr Zuma has said.

"It depends on whether companies give us a reasonable, competitive price."

Dr Shisana said parallel importing was simply letting market forces work and this included the international market. Quality control would not suffer, she said.

"We found that tender prices from the pharmaceutical industry (locally) were 21 percent higher than what we could get on the international market."

An amendment to the Pharmacy Bill allows anybody to own a pharmacy, provided that it is under the continuous supervision of a pharmacist. Concern has been expressed that large chainstores will put small pharmacies out of business.

Dr Shisana says, however: "It is not the Government's responsibility to protect business interests in the private sector. It's an unhappy and sorry state that the Government has protected certain professions."

The pharmacy council told the hearings it was concerned not so much at the principle of pharmacy ownership, but at the wording of the bill. The council and the health department are meeting to iron out problems.

The Medicines Control Council will also be affected by the new laws which make it a legal entity for the first time (meaning it can be sued separately from the health department) and allow it to retain revenue from registering drugs.

Peter Eagles, vice-chairman of the MCC, said the council had reservations as to its constitution and the fact that the Minister of Health had the final say over its executive committee. He said amendments would be detrimental to the council's objectives of safety, efficacy and quality unless certain wording was changed.

Differences between the health department and the MCC about the bill were such that Dr Nkomo had ordered that the two parties to meet again to work out their major differences.

Through the three mornings of hearings there were murmurings and rumblings that Dr Zuma was being given extensive powers to control the sale of medicines in South Africa, a perception which was denied by health department officials who said it was rather a consolidation of powers.

Concern was also voiced at the hearings that the legislation was being rushed through the parliamentary process without adequate consultation.

Democratic Party spokesman on health Mike Ellis, who sits on the portfolio committee, said handling three complex bills at the same time within a short time was a problem.

This was echoed by the three councils presenting their views. They said that although there had been extensive consultation up until the bill was drafted, they had not seen final drafts in time to consult adequately with the department on changes.

Dr Shisana responded by saying: "We are doing three bills at the same time because they are interrelated. Our intention is to ensure consistency."

However, there is clearly also a sense of urgency as a delay in passing the bills would be a delay in bringing drug prices down.

"We would like to move rapidly for transformation to reduce costs of medicines for our people," Dr Shisana told the hearings.

Chairman of the portfolio committee Abe Nkomo supported this, saying: "Now is the time of the depths of the transitional period. It can't be business as usual."

UK drug producers join battle against bill

BD 3/6/97

Kathryn Strachan

BRITISH pharmaceutical manufacturers joined the battle against Health Minister Nkosazana Zuma's proposed medicines legislation yesterday, stating their objections in a letter sent to Zuma and to Deputy President Thabo Mbeki.

The Association of the British Pharmaceutical Industry also raised the issue with the UK government, arguing that the proposed bill violated international trade rights agreements.

In the US, drug manufacturers scheduled a meeting last night between several companies and SA ambassador Franklin Sonn. The International Federation of Pharmaceutical Manufacturers joined the offensive last month when its president, Glaxo Wellcome worldwide CE Sean Lance, said the proposed legislation would result in disinvestment in SA.

The US industry's trade association, Pharmaceutical Research and Manufacturers of America (Pharma) said yesterday the next step would be to testify at the parliamentary hearings due later this week.

Pharma vice-president Tom Bombelles said US government representatives had raised the matter with their SA counterparts at a World Trade Organisation meeting last week.

Sapa reports that Pharmacare Limited, the pharmaceutical division of SA Druggists, has come out in support of Zuma's intention to promote the use of generic medicines above more expensive branded drugs, where appropriate.

But the company was concerned by Zuma's intention to import cheap generic medicines which gave the impression SA was unable to satisfy its own requirements for competitively priced generic products.

By Charles Schulz

Court challenge to teacher redeployment

BD 3/6/97

Linda Ensor

CAPE TOWN — The legality of Education Minister Sibusiso Bengu's teacher redeployment strategy was challenged in the Cape High Court yesterday by Grove Primary School, whose action was supported by more than 70 other Western Cape schools.

Placard-wielding members of the SA Democratic Teachers' Union, which supported redeployment, thronged the court entrance before proceedings began, to protest against the application.

The court action was brought against Bengu, who is opposing it, the education MECs of the nine provinces and 21 other signatories to the Education Labour Relations Council. The central issue concerned the right of school governing bodies to choose teachers rather than have them prescribed by MECs from lists of redeployable teachers.

In terms of the scheme, teachers who voluntarily agreed to redeployment ranked highest on the list of those eligible for employment, followed by compulsory redeployees ranked by the last in, first out principle. If a school disagreed with the teacher allotted to a post, its objection would be considered only on the basis of "curriculum requirements".

"Provision of the best quality teachers plays absolutely no role and schools have no choice worth the name," Grove's counsel Gerrit van Schalkwyk SC argued. The strategy was based on the questionable principle that excess teachers in employment had a superior constitutional right to employment than teachers who had left the profession, and graduates.

Grove has applied for agreements on redeployment to be set aside on the grounds that they were ultra vires. It has also argued that Bengu's promulgated extension of these agreements to all employers and employees in the educational sector who were not party to the agreements was unlawful.

Van Schalkwyk noted that Bengu had extended the provisions of the agreements under the Education Labour Relations Act on November 22, although this act was repealed by the Labour Relations Act which came into force on November 11. Bengu had also acted contrary to provisions of the National Education Policy Act in concluding agreements on redeployment at the education labour relations council.

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Generic drug headaches

(96) CT(BR) 3/6/97

FRANÇOISE BOTHA

Johannesburg — South African pharmaceutical companies are strongly divided over support for proposals by Nkosazana Zuma, the health minister, to promote the use of generic drugs rather than branded products.

The proposal, which is contained in the draft Medicines and Related Substances Control Amendment Bill, is aimed at reducing the cost of medication through the increased use of unbranded, or generic, drugs.

South African Druggists and Ranbaxy, the generic drug makers, came out in strong support of the proposal yesterday, which would see them gain market share from multinational branded-drug rivals like SmithKline Beecham, Glaxo Wellcome and Novartis.

Kobus Nel, the chief executive of Pharmacare, South African Druggists' pharmaceutical subsidiary, said: "Generic substitution is indeed one of the most sensible ways of ensuring adequate primary healthcare for all. Unfortunately, the perception is that generics are of lower quality than branded ethical drugs. This is simply not true."

Terry Lee, the chief executive of Ranbaxy South Africa, said there was strong support for Zuma's proposal and generic drug substitution was "highly likely" to be introduced.

Outrage at cabinet stand on rhino trade

(56) CT 4/6/97

THE Environment Ministry had not been consulted about a government decision to support renewing international trade in ivory and rhino horn, Environment Minister Dr Pallo Jordan said yesterday.

He told a meeting of the National Assembly's environment committee that the cabinet would not change its mind.

The issues are to be raised at next week's meeting of the Convention on International Trade in Endangered Species in Harare.

Jordan promised to brief the cabinet tomorrow about the committee's concerns.

Members of the committee said they were disturbed that the executive had reached a decision without consulting Parliament or the public. Renewing the trade could lead to widescale poaching.

The Southern African Development Community had resolved last year to ask that elephants be downgraded from "endangered", but SA had since decided not to include its own herds, Jordan said.

The proposal to renew trade in rhino horn had been made by the Natal Parks Board, which envisaged harvesting horn from living white rhino to halt poaching.

The present policy on elephant and rhino had curtailed illegal trade, but had not answered the question of how best to use Africa's natural resources and meet developmental needs.

"I think it is within the power of the minister to turn this around," Mr Nic Koornhof (National Party) said. "We need more time (and) consultation."

Mr Aubrey Mokoena (African National Congress) said the committee could not allow itself to be sucked into the depletion of natural resources in Africa.

The African director of the International Fund for Animal Welfare, Mr David Barritt, said later he was alarmed by the cabinet's decision. "How can we square that with the new democratic SA?" — Sapa

Gauteng seeks delay in implementing new system

CT 4/6/97 (50)

JOHANNESBURG: Gauteng's education authorities have called on Minister of Education Dr Sibusiso Bengu to postpone introducing the new curriculum next year as its schools will not be ready to do so.

Teacher unions, which have said teachers throughout the country will not be ready to implement the curriculum next year, have welcomed the call.

It is believed that the Western Cape and the Eastern Cape are to make similar reports to Bengu to persuade him to delay the process.

Bengu tried to reassure teachers yesterday that they would learn the new curriculum as they taught it. However, he opened the door to a postponement.

"If in our assessment we are not ready, we will not hesitate to inform the public accordingly," he said.

It was decided last year to introduce the new system only in Grade One and Std 5 next year.

Speaking at an education conference here yesterday, the co-ordinator for the Gauteng Department of Education's Institute of Curriculum Development, Mr Haroon Mohammed, said the province had assessed its state of readiness and decided the curriculum should be delayed.

'LEARN ON JOB': Sibusiso Bengu

"We will manage implementation in Grade One, but it is doubtful we can manage Grade Seven (Std 5)."

It would be recommended to Bengu that the curriculum be introduced in Std 5, as well as Grade Two and Std 6, in 1999.

"Given the 48 000 teachers we have to reach in the province, it would be better to set a strong foundation with Grade One," Mohammed said.

The South African Democratic Teachers' Union, although keen for the new system to be introduced as soon as possible, said it might be more realistic to delay it.

The National Professional Teachers' Organisation of South Africa's executive director, Mr Andrew Pyper, said he was "delighted" by the decision by Gauteng authorities.

"We hope their recommendation will bring about what we have been requesting," he said.

The Association of Professional Teachers also welcomed the move.

Asked at the conference if the government would ensure teachers understood the new system before it was implemented, Bengu said it would be necessary to do so. He did not want criticism that educators "are not informed because they are going to be informed". — Own Correspondent and Sapa

CT 4/6/97

Drug companies decry forced generic medicine

(96)

DURBAN: DRUG companies have slammed the government for trying to enforce the use of generic medicines and have warned that the importation thereof could damage the local manufacturing industry.

The Pharmaceutical Manufacturers Association (PMA) said it was "concerned" with proposed legislation that would make generic substitution compulsory.

PMA chief executive Ms Mirryena Deeb said in a statement that although industry was not opposed to the use of generics it was against measures that forced the use of generics because this amounted to "government favouring one competitor ahead of another".

The draft medicines bill, to be debated in Parliament on Friday, states that the pharmacist should substitute every prescription with a cheaper generic, and must also inform the patient of the benefits of substitution. — Own Correspondent

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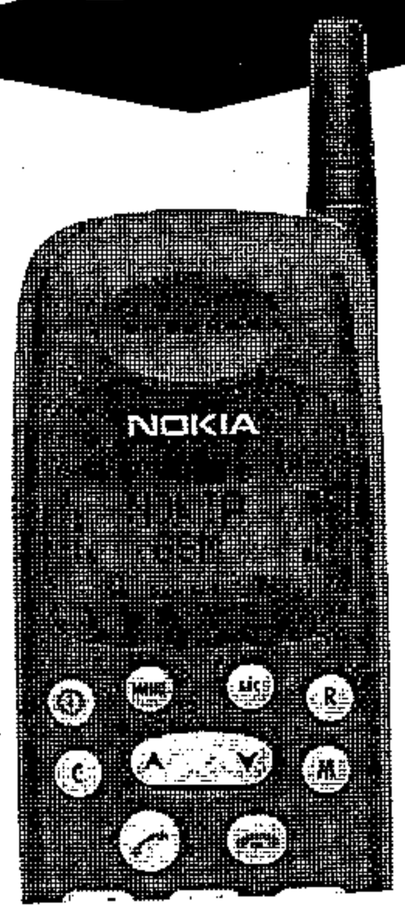

Leading businessman issues warning on SA investment

Tim Cohen

(96) BD 4/6/97

EDINBURGH — The edge was taken off a major SA investment effort yesterday when a leading member of the SA pharmaceutical industry issued a serious warning on investing in SA.

In stark contrast to many other forums at the Europe SA '97 conference where investors were encouraged to invest in SA, SmithKline Beecham CEO Günther Faber warned of a "total socialisation of healthcare in SA".

Faber surprised delegates by saying SA's small but vibrant pharmaceutical sector was "under threat".

Faber said this was because of proposed legislation "which flies in the face of official government policy of an economy based on free-market principles". The legislation had "scant regard" for intellectual property rights and was contrary to the Trips agreement that government had recently become party to, he said.

"Naturally, from an investment point of view, it will relegate SA's importance in terms of a base as a springboard into Africa."

The health department had decided to ignore the government's macroeconomic policy which embraced free-market principles, to "use socialistic policies" to drive forward its own laudable primary healthcare policy for SA.

But despite the gloomy prognosis, Faber said prospects were good and investors ought not to be "despondent".

Finance Minister Trevor Manuel defended the health department, saying as far as government was aware, the legislation did not contravene the Trips agreement.

He chided the industry for speaking in general terms about the free market, but had not come forward with specific problems it had with the legislation. It was up to the industry to show how the legislation contravened intellectual property rights, he said.

Furthermore, the industry had not presented an overall philosophy of where it was headed. "So far we have only heard lobbying," Manuel said.

Doctors get heard on medicines bill

CT 6/6/97 (96)

CAROL CAMPBELL

POPULAR moves by Health Minister Dr Nkosazana Zuma to make medicine in South Africa cheaper will be questioned by the medical fraternity at a special public hearing in Parliament today.

Zuma has repeatedly said the price of medicine in South Africa was "among the highest in the world" and the provision of safe, effective and affordable drugs in the right quantities to the whole population was a national priority.

Medical sources say the price of medicine in South Africa is about four times higher than it is in most overseas countries and Professor Peter Folb, chairman of the Medicines Control Council, said prices differed by as much as 1 000% among some dispensing doctors.

A spokesman for Zuma's office said the pharmaceutical industry refused to give the minister a full breakdown of who makes how much in the medicine trade.

Major players in the pharmaceutical industry, pharmacy owners, dispensing doctors and representatives of the nursing profession will make their representations to the Parliamentary Health Committee, who then has to decide if the Medicines and Related Substances Control Bill should be changed.

Issues raising hackles are:

- Zuma's plan to import cheap medicines for use in public hospitals and clinics — a practice which is common in Europe and Africa.
- Legalising generic substitution. This means that pharmacists will have to offer patients cheaper generic medicines as an alternative to medicines prescribed by their doctor. If doctors don't want an alternative they will have to write this on the prescription.

Dr Mohamed Adam, secretary of the National Convention of Dispensing said doctors would fight in court if necessary for their constitutional right to dispense medicines.

Adam said he agreed no one should make a profit out of selling medicine, but to stop doctors charging cost plus a dispensing fee was wrong.

Adam said doctors were questioning the safety of generic substitution and whether or not nurses and pharmacists should be permitted to prescribe drugs (recommended in the new bill).

Spokesman for the Medical Association of South Africa (Masa), Ms Marileen van Wyk, said: "While we support generic prescribing, we oppose the introduction of an obligation on pharmacists to sell generic products, under certain circumstances, without consulting the prescriber."

She said it was unacceptable that the bill envisaged absolving a pharmacist from liability if a patient was harmed for not receiving prescribed medicine.

Masa also opposes restrictions on doctors to dispense medicine to their patients. "If licensing is to be introduced it should be done by doctors' professional board which must take responsibility ... not by a government official such as the director-general of health, as envisaged."

MEDICINES CONTROL FURORE

FM 6/6/97

Trademark war over Zuma drug plan

Manufacturers claim the Health Minister's drive for cheap medicines could harm SA's trading status (96)

The International Trademark Association has added its voice to the barrage of criticism against Health Minister Nkosazana Zuma's proposed drug reforms, warning that they contravene the basic principles of trademark law and threaten foreign investment in SA.

The Medicines & Related Substances Control Amendment Bill, now before parliament's portfolio health committee, aims to make medicine more affordable but has been slammed from all sides.

This week, powerful Washington-based lobby Pharmaceutical Research and Manufacturers America (PhRMA) joined forces with local pharmaceutical manufacturers to fight the Bill, which they say violates their intellectual property rights and threatens the viability of the domestic industry.

It is believed that the US Department of Commerce backs PhRMA's case and is prepared to take its protest to the World Trade Organisation unless Zuma moves to reassert trademark protections.

There were signs earlier this week that the Health Department was beginning to bend to pressure. The parliamentary health committee instructed the Medicines Control Council (MCC — SA's independent drug regulatory authority) to get together with the department and review the MCC's concerns in anticipation of the committee's public hearings on June 6. These closed-door meetings have resulted in substantial changes to the Bill.

"The department has accepted our view on a number of points and, while we have had to accept their points, I am satisfied that we have made progress," says MCC chairman Peter Folb. He refuses to give details, but industry sources say the changes will give the council greater control over cheaper drug imports.

The usually conservative council made a damning submission on the Bill to the portfolio committee last week, saying it contains "serious and fundamental flaws which could weaken the medicine control process."

In a letter to the committee dated May 29, International Trademark Association president David Stimson objects to the provision which prohibits the sale of any medicine to the State if its brand name appears on the label.

He says it violates SA's obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights and removes the competition that spurs manufacturers to improve their products.

Stimson says that though the Supreme Court's 1996 decision in the McDonald's fast food case was a step in the right direction, trademark owners have had good reason in the past to be concerned about trademark protection in SA.

"By contravening the basic principles of trademark law, the Bill's passage would suggest to trademark owners everywhere that their valuable intellectual property assets may still be at risk in SA," he says.

Arnold Pronto

Nkosazana Zuma . . . *resisting pressures to drop drugs plan*

PhRMA represents 16 US-based multinationals with investments worth about R5bn in SA. They make up more than half of the domestic pharmaceutical industry, which turns over R10bn annually.

PhRMA has taken its concerns to the highest level, including the US-SA Business Council (the secretariat of the business committee of the US-SA Binational Commission chaired by US Vice-President Al Gore and SA Deputy President Thabo Mbeki), SA Ambassador Franklin Sonn, the US State Department, members of the US Congress, the US Patent and Trademark Office and the International Trademarks Association.

The industry's prime concern is the proposal that would in effect allow any importer to buy a multinational's drugs outside its controlled distribution networks in order to take advantage of the substantial differences in drug prices between countries.

BITTER MEDICINE

How Zuma's proposals would weaken health controls

Existing procedures

- Raw materials, dosage form & packaging need approval.
- Manufacturing procedures & controls are inspected.
- Quality controls continuously monitored.
- Duration of shelf life tested.
- Innovative medicine requires evaluation of all international studies on animal & human tests.
- Generic medicine must be proved to have comparable therapeutic effects.
- Medicines must be registered.
- All drugs continually monitored by Medicine Control Council

Zuma's proposals for parallel imports

- Draft law states imports of medicines registered in SA & sourced from a different country will be considered already registered.
- No specified checks on source, quality or integrity of medicine.
- Medicine Control Council has no control of imports.
- No data needs to be submitted.
- No other criteria outlined.
- No clear liability for faulty medicine (who will withdraw faulty products?)

Parliament to hear evidence on pharmacy amendment bill

(96)

Jacob Dlamini

BD 9/6/97

CAPE TOWN — The parliamentary health committee will hear evidence today on the controversial pharmacy amendment bill, amid fears of possible legal action against government by the pharmaceutical industry and dispensing doctors should it become law.

The Pharmaceutical Manufacturers' Association warned on Friday that it would not countenance intervention which would foster unfair competition and infringe intellectual property rights. Several organisations said the bill violated the constitution.

The bill is part of legislation which includes two years of vocational training for medical students, restrictions on doctors' ability to dispense and the introduction of measures intended to allow laymen to run pharmacies.

Six opposition parties accused the African National Congress (ANC) of seeking to push through Parliament the new legislation during parliamentary hearings on the medicines and related substances control amendment bill on Friday. The parties said they would request President Nelson Mandela's intervention in the matter.

The Democratic Party, National Party, Inkatha Freedom Party, Freedom Front, Pan Africanist Congress and the African Christian Democratic Party staged a brief walkout from the hearings following a row with parliamentary health committee chairman Abe Nkomo over the 10 minutes allocated for submissions.

DP spokesman Mike Ellis said the six opposition parties had also jointly decided to call for the extension of the Interim Medical and Dental Council's term of office by six months to allow for further discussion of the bill.

The committee heard submissions from deans of medical schools and junior doctors, who objected to the lack of consultation and said it would be too soon to introduce vocational training at the beginning of next year.

The Interim Medical and Dental Council said it was opposed to health department plans to assume control over the licensing of dispensing doctors as such licensing was a professional practice matter which should be done by the council. The bill also came under attack from the Free Market Foundation, with spokesman Temba Nolutshungu saying sections of it would lead to unwarranted state interference in the marketing of medicines.

'BOLD' NEW PLAN

Medicine law 'would save billions'

(96) CT 9/6/97

BATTLE LINES are drawn between medical aid schemes and the pharmaceutical industry over the Health Minister's plans. **CAROL CAMPBELL** reports.

HEALTH Minister Dr Nkosazana Zuma's moves to make medicines in South Africa cheaper were "bold" and "courageous", and would save medical aid schemes "billions of rands".

Dr Aslam Dasoo, the director of policy for the Representative Association of Medical Schemes (Rams) made these comments at a public hearing on changes to South Africa's medicine laws.

"The cost benefit to medical schemes ... will translate into lower contributions by workers and employers," he said at the hearing which was held in Parliament.

Zuma plans to import cheap, quality medicines from factories overseas at prices far lower than she is being offered in South Africa.

The Cape Times has established that the state buys most of its medicines on local tender. The cheapest South African supplier acquires stock and sells it to the government for about one tenth of the private sector price.

This year the Department of Health will spend about R20 billion on public health. About one-third of this will be on medicines, Dasoo said.

The health minister is also demanding that pharmacists offer private consumers cheaper generic medicine as an alternative to brand-name drugs prescribed by their doctor.

She wants to cut out "bonusing", a practice in which a doctor "wins" an overseas trip or a gift from a pharmaceutical company for repeatedly prescribing its drugs.

Dasoo said medical aid schemes would in future insist on buying medicines in a "normal free market" and not in the current "disempowered" and "subservient" manner.

"Rams is satisfied that the Medicines Control Council, which is a world-class regulatory authority, will protect the citizens of the country as it is obliged to do, by preventing any questionable drug to be improperly registered in South Africa."

The Pharmaceutical Manufacturers Association, represented by Mrs Mirryena Deeb, told the Cape Times that the industry in South Africa had an annual turnover of R10 billion and 80% of this came from foreign investment.

"These laws are frightening investors off. Already 10 factories have closed in the past six months because the new laws are perceived as unfair. What Dr Zuma is doing to the pharmaceutical industry in this country is at odds with the government's macro-economic policy."

The local pharmaceutical industry, which is subjected to stringent quality checks by the Medicines Control Council, has also accused Zuma of endangering the lives of South Africans by sourcing drugs from "unknown" factories.

An international expert on drug counterfeiting warned that seven percent of pharmaceuticals worldwide were counterfeit. In the Philippines it was established that parallel imports were a major source of these "dud" drugs.

Deeb criticised the way the parliamentary portfolio committee handled the public hearings on the bill.

Dr Gunther Faber, chief executive of SmithKline Beecham International, interrupted a business trip to Europe to address the meeting, but was asked to speak only at 7pm when only five of the 26 members of the portfolio committee were still present.

● The Cape Times will carry a special report on counterfeit drugs tomorrow.

What Zuma has:

- At the moment the state buys medicines on local tender, which means a company based in South Africa sources the drugs from overseas, imports them and then sells them to the government.
- Right now pharmaceutical companies offer doctors and pharmacists "bonuses" for selling their drugs to patients. Generics, which are cheaper than brand-name drugs, are not always offered even though they are as good.

What Zuma wants:

- In future Zuma wants the state to source drugs for the public sector from factories overseas – cutting out all middlemen. She believes she will be able to get medicines at a much lower price she is currently paying. This is called "parallel importing".
- Zuma wants all pharmacists to offer patients the choice of taking a cheaper generic drug other than the brand-name drug which their doctor prescribes. This is called generic substitution.

The problems:

- Unless this system is scrupulously controlled the state could unwittingly import counterfeit drugs. Overseas factories could "dump" their excess drugs in South Africa which will upset local pharmaceutical economics.
- Pharmaceutical companies are concerned that their trademarks on medicines are not being respected by Zuma.
- The problem with generic substitution is that if something goes wrong and the patient gets sick because she took a drug not prescribed by a doctor but suggested by a pharmacist, the pharmacist will not be held liable.
- Local pharmaceutical companies say Zuma will not be able to source drugs directly from their factories elsewhere in the world which means she might be forced to go through a "middle-man" and expose herself to the risk of buying "dud" drugs.

How are medicine prices made up:

- One of Zuma's major problems with the pharmaceutical industry is that they are not transparent about how the cost of a medicine is worked out.
All she knows is that wholesalers mark-up the price by 17,5% and pharmacists by about 50%. However, medicine prices are not regulated and mark-ups vary by as much as 1 000%. Also, she does not know how much it costs to make a medicine and how much it is then sold for.
- Zuma wants a pricing committee to monitor the price of medicines in the country. She is also considering other cost-curbing measures like set dispensing fees and placing limits on the prices manufacturers may charge.

Bitter battle looms over ivory trade ban

(56) CT 9/6/97

HARARE: A bitter battle over a proposal to resume trade in African elephant ivory looks set to dominate a world conference on endangered species, opening in Zimbabwe today.

The 10-day Convention on International Trade in Endangered Species (Cites) has attracted more than 2 000 delegates, including members of the world's leading environmental watchdogs.

Many have already declared their position on the ivory dispute and focused media attention on the issue — much to the irritation of Cites secretary-general Mr Ezgrev Topkov.

"For us, all the issues on the agenda are important, but for many people the conference has become a conference on elephants alone," Topkov told a press conference last week.

"We have 115 agenda items ... The media should not report only on elephants," he complained.

The elephant debate has been brought to the fore by a proposal from three Southern African states — Botswana, Namibia and Zimbabwe — for the partial lifting of a seven-year-old ban on ivory trade.

The three countries and their supporters, notably Japan, say they must be allowed limited trade because their elephant herds, now estimated at around 150 000, are rising steadily.

Since the ban was imposed these countries have accumulated nearly 100 tons of ivory from annual culls and legally hunted trophies.

But the proposal is strongly opposed by some influential green movements and countries, who argue that lifting the ban will leave elephants at the mercy of poachers. — Reuter

the weekend.
De Beer, who worked with Klerk loyalist Fanus Schoeman, would have speeded up the pace Elsewhere, NP Eastern Cape head council member and about a Sources

Pharmaceutical industry public hearings are farcical, says DP

BD 10/6/97 St (96)

Jacob Dlamini

CAPE TOWN — The parliamentary health committee has come under fire over its handling of public hearings on draft legislation intended to reform the pharmaceutical industry, with the Democratic Party (DP) calling the proceedings "farcical".

Yesterday DP spokesman Mike Ellis walked out of hearings on the Pharmacy Amendment Bill, saying it was a waste of time discussing the legislation without the amendments likely to be added to it as a result of an agreement between the health department and the Interim Pharmacy Council.

The council and the department earlier announced that they had agreed on a number of proposals which were likely to alter the bill. The legislation is designed to lower the cost of drugs by opening up the ownership of pharmacies to laymen.

In terms of the agreement, the department will state clearly the conditions a lay person must satisfy in order to qualify for ownership of a pharmacy. The department will also be required to define the terms under which a lay person's licence to operate a pharmacy may be revoked.

The changes are likely to be added to the bill before it goes through parliament later this year.

The committee heard evidence from various organisations opposed to the lay ownership of pharmacies. The SA Association of Community Pharmacists said laymen and chain stores lacked the professional ethos needed to run pharmacies and would be driven purely by economic imperatives. Family Practitioners' Association spokesman Bharutih Seetharam said lay ownership would expose customers to counterfeit, stolen and expired drugs. He said chain stores would muscle in on the trade and force community pharmacies to close down.

Six opposition parties said they rejected the existing bill and called for the extension of the Pharmacy Council's term of office, which expires in October, by six months. The DP, National Party, African Christian Democratic Party, Inkatha Freedom Party, Freedom Front and Pan Africanist Congress said that the extension would remove the need for Parliament to pass the legislation this year and would allow for more consultation.

However, council president Johan van der Walt said he would be satisfied if the bill was passed this year. Van der Walt said he would not support the extension of the council's term of office, as it had fulfilled its mandate.

But Van der Walt warned that the bill's implementation might have to be delayed if parties failed to reach agreement on the other two pieces of legislation — the Medicines and Related Substances Control Amendment Bill and the Medical, Dental and Supplementary Health Service Professions Amendment Bill.

Van der Walt said there were clauses in the three bills which were interdependent and that these would be invalid if the bills were enacted separately.

[illegible] the two-year limit

Medicine law hearings 'a farce'

CT 10/6/97 (96)

HEALTH WRITER

PUBLIC hearings on South Africa's new medicine and pharmaceutical laws have been dismissed as "a farce" by opposition parties who claim the ANC is riding roughshod over opposing views to push through fundamental and controversial changes to health legislation.

Yesterday Democratic Party health spokesman Mr Mike Ellis walked out of the public hearing on the Pharmacy Amendment Bill after his appeals for the process not to be rushed were dismissed by committee chairman Dr Abe Nkomo.

Ellis and other opposition MPs also walked out of a hearing on Friday when the committee was hearing evidence on whether or not junior doctors should do two years' vocational service.

"Bills which have such far-reaching implications cannot be rushed," Ellis said.

Nkomo told the audience that the hearings were not the place for political bickering and appealed to members to "listen" and not drag the committee fighting into a meeting intended for civil society to air its views.

Despite his appeals, several members of the pharmaceutical and pharmacy industry sided with opposition parties and expressed concern that the committee did not fully appreciate the consequences of the changes proposed.

Yesterday's hearings focused on the ownership of pharmacies.

Minister of Health Dr Nkosazana Zuma wants better distribution of medicines to rural areas and townships and has proposed that businessmen and not just pharmacists be allowed to own pharmacies.

By doing this she hopes to encourage entrepreneurs to move into unserviced areas.

Mr Ivan Kotzé, chief executive of the Pharmaceutical Society of South Africa, argued that in certain situations the wording of the act was vague and created loopholes that could be abused by unscrupulous businessmen.

"We agree there should be a deregulation of ownership but only in certain circumstances. If you allow total deregulation there is no way the small township pharmacies will survive."

Talks with the health department had been encouraging and an indication that pharmacists represented by the society and Zuma were thinking along the same lines, but the spirit of those talks was not reflected in the amendments to the bill, he said.

The health committee will reconvene on June 17 to discuss submissions on amendments to the new bills.

CAPE TIMES
TUESDAY, JUNE 10, 1997 ★

'NO PROTECTION AGAINST FAKES'

Drug imports may open Pandora's Box — expert

CT 10/6/97

(96)

AN INTERNATIONAL EXPERT on counterfeit drugs says the cost of checking imported drugs will outweigh any savings, Health Writer **CAROL CAMPBELL** reports.

IMPORTING cheap medicines, as Health Minister Dr Nkosazana Zuma proposes to do, will risk counterfeit drugs flooding into South Africa if the process is not controlled scrupulously, an international expert on counterfeit drugs has warned.

Under the present system the South African Medicines Control Council (MCC) knows exactly where medicines are made and, if there is a problem, can trace the drug back to its factory source.

The MCC has advised the minister it is essential that the present system of controls on all imported medicines, regardless of their source, be kept.

Failure to do so would soon lead to the country being flooded by inferior and counterfeit medicines.

Speaking from London yesterday, Mr Frank Madsen, director of international security for the British pharmaceutical company, Bristol-Myers Squibb, said it was impossible to tell, by looking at it, if a drug was authentic.

Madsen has been involved in setting up the new Pharmaceutical Security Institute which, from its secret venue in Italy, is co-ordinating international efforts to stamp out dangerous "dud" drugs.

"The packaging, the batch number, everything looks exactly like the real thing — (but) the consequences of taking a counterfeit drug can be lethal.

"(Counterfeiting medicine) is a dangerous business. It is run by organised crime syndicates."

At a meeting of the World Health Organisation and the International Pharmaceutical Manufacturers' Association (IFPMA) in 1995, it was estimated that 15% of the pharmaceuticals traded worldwide was counterfeit.

The head of the MCC, Professor Peter Folb, said although this figure was not based on sound data, it was accepted as correct.

"Counterfeiting in medicines is big business," he said.

"(These drugs) are likely to be ineffective and may be unsafe.

"Dr Zuma's proposal is that once a company has been approved as a source of medicines for parallel importation, such medicines — regardless of their origin — may be brought into the country by the company, provided the company's name is attached.

"There can be no adequate control of this situation. There is every prospect of its being exploited by unscrupulous companies."

Madsen warned of Mafia-style counterfeiting operations in India, China, Nigeria and Brazil, but emphasised the problem was impossible to monitor.

"The counterfeiters make their medicine in one country, print the packaging in another, bring the two together in a third and sell it in a fourth. If countries like the United Kingdom and the United States, with their powerful legislation, can't control counterfeiting, who can?"

Madsen has sent a written submission on counterfeit drugs to the parliamentary portfolio committee on health.

South Africans could be exposed to these drugs if international pharmaceutical companies with local divisions bar Zuma from buying medicines from their factories elsewhere in the world.

"She will have to go through unscrupulous middlemen and that is where there could be a problem."

Madsen said the cost of setting up checks and balances to protect Zuma from counterfeit drugs would be so high that she might as well continue to procure medicines by local tender.

In the Philippines, 8% of all pharmaceuticals sold were counterfeit. About 9% of these were parallel imports and often of "spurious" origin.

"Some, unfortunately, could be described only as lethal. These were injectable antibiotics that contained no active ingredient or the wrong one.

"They all contained non-sterile water for mixing the product prior to injection."

DP slams proposed Pharmacy Amendment Bill as 'farcical'

(96)

Medical school deans say graduates too inexperienced to go out on their own

Star 10/6/97

By Jovial Rantao and Janine Simon

Public hearings on the Pharmacy Amendment Bill, which aims to cut drug costs by opening ownership of pharmacies to all, were yesterday labelled "farcical" by Democratic Party health spokesman Mike Ellis.

The bill is one of three controversial pieces of legislation geared to support the Health Department's National Drug Policy and revolutionise the health and pharmaceutical sectors.

The other two, the Medicines and Related Substances Control Bill and the Medicine, Dental and Supplementary Health Service Professions Amendment Bill, were the subject of fierce exchanges that led to a walkout of the hearings by the five opposition parties on Friday.

The legislative process is under pressure because the terms of office of the Interim National Medical and Dental Council and the Interim South African Pharmacy Council (ISAPC) end in October.

Yesterday changes to the Pharmacy Amendment Bill, agreed on by the ISAPC and the Health Department, were tabled at the beginning of the hearings. They relate to among others, conditions of ownership of pharmacies.

Ellis walked out of the hearing, saying the legislation without the amendments would be a waste of time.

But ISAPC president Professor Johan van der Walt and Director-General of Health Dr Olive Shisana were optimistic that all three bills would become law before December.

The Junior Doctors' Association of SA and the Intern Action Coalition Group intend taking legal action against the Health Services Bill if it is unchanged at the time of the second reading scheduled for next month. The bill obliges medical graduates to do two years' vocational training.

They say terms of training have been altered without notification, that there will be inadequate supervision of posts, and that the training period will become too long.

But the Health Department has hit back, saying the extra two years allows graduates to gain experience and skills while earning at least R77 903 a year.

None of the deans of medical schools believed their graduates were "safe" to practise independently immediately after their intern year.

Senior Lecturer in Anthropology
Rhodes University

cc Mr Neil Papenfus
Development Office
Rhodes University

US business calls on Parliament to halt proposed medicines legislation

(96) BD 11/6/97

Jacob Dlamini

CAPE TOWN — The American Chamber of Commerce (AmCham) yesterday called on Parliament to halt the proposed health reforms, and predicted dire consequences if this did not happen.

AmCham called for the changing of the Medicines and Related Substances Control Amendment Bill, saying it was not in SA's international trading interests.

The chamber said the bill, which seeks to improve access to health care by lowering the price of drugs through generic substitution and parallel importation, was a violation of international trading practices.

AmCham spokesman Patrick McLaughlin said the provision for the removal of brand names from products sold to government by pharmaceutical companies was a violation of trademark rights.

The provision would set a dangerous precedent for international property rights and could have serious repercussions from concerned US companies in SA.

The bill would, if it became law, affect 263 US companies with a combined employment of 280 000.

He said it would be up to AmCham's members to withdraw from the country and SA stood to lose millions if this happened.

The bill implied that the health ministry wanted to sanction practices which contravened SA legislation and international norms.

The bill also indicated to international investors that their intellectual property assets would not be protected.

Meanwhile, the Democratic Party's health spokesman Mike Ellis told University of Cape Town medical students and interns yesterday that the Medical, Dental and Supplementary Health Services Bill, seeking to introduce vocational training, was draconian.

Ellis said it was authoritarian for government to ask medical graduates to commit themselves to vocational training. He warned that the bill would fail.

However, Representative Association of Medical Schemes (RAMS) policy director Aslam Dasoo welcomed the health reforms. He said the proposed bills would help reduce RAMS' annual R6bn drug bill.

RAMS was more interested in the rights of South Africans who had been denied, rather than in the intellectual property rights of pharmaceutical manufacturers, Dasoo said.

South Africans had been denied access to affordable health care through high prices for drugs which were protected by trademark laws, he said.

While government is free to procure generic drugs from any source in the world under the existing Medicines Control Act, it is prohibited from buying trademark drugs from another source if they are registered in SA.

Cabinet to take another look at Zuma health bills

(93)

CLIVE SAWYER
POLITICAL CORRESPONDENT

ARG 12/6/97

Protests by parliamentary opposition parties against Health Minister Nkosazana Zuma's controversial package of health bills has paid off with her announcement that the measures will be temporarily withdrawn.

The bills would be submitted again to the Cabinet next week, she said.

Minutes after her announcement in Parliament yesterday, opposition parties called for a fresh round of public hearings on the bills.

Dr Zuma, in her special announcement to the National Assembly, made it clear she still fully backed the intention of the bills.

Health should no longer be the sole privilege of those who had medical aid or the money to pay.

South Africans were paying among the highest prices in the world for medicine, she said.

Her bills would enable access to quality medicines on the global market and open the running of pharmacies to non-pharmacists.

Cabinet to take another look at Zuma health bills

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Zuma withdraws controversial bills

BD 12/6/97 (96)

Jacob Dlamini

CAPE TOWN — Health Minister Nkosazana Zuma has backed down on her plans to introduce sweeping health reforms, by withdrawing three controversial bills from Parliament.

Zuma told Parliament yesterday she was withdrawing the legislation so she could study the submissions made to Parliament's health committee.

The legislation is aimed at introducing two years of vocational training for medical students; allowing for the lay ownership of pharmacies; allowing generic substitution where cheaper drugs are available; and allowing the parallel importation of drugs at competitive prices.

The Pharmacy Amendment Bill, the Medicines and Related Substances Control Amendment Bill and the Medical, Dental and Supplementary Health Service Professions Amendment Bill were withdrawn.

The announcement comes after opposition from political parties, the pharmaceutical industry, medical students and foreign companies with interests in the SA health industry.

Zuma said she wanted to make sure genuine concerns and suggestions expressed during the hearings on the bills were taken into account before they were resubmitted to the cabinet next Wednesday. The need to improve access to affordable health care superseded all sectional interests.

Zuma's move also follows mounting pressure from opposition parties for the bills to be withdrawn. They said another round of public hearings would have to be held once the bills had been resubmitted to the cabinet.

The Representative Association of Medical Schemes (Rams) expressed regret that the bills had been withdrawn. Rams policy director Aslam Dasoo said he hoped the bills would still be passed this year. He understood Zuma may have been motivated by fear of possible litigation from opponents of the bills, which could have tied the bills down.

Kathryn Strachan reports that the Pharmaceutical Manufacturers' Association questioned whether one week was enough time to make meaningful changes.

The Medicines Control Council said the council unreservedly supported the principles underpinning the legislation, but had problems with technicalities which would be vital to the ultimate impact of the legislation.

Junior Doctors' Association of SA spokesman Mark Sonderup said the announcement was "very encouraging. It is a sign that they are at least taking note of what we all have submitted."

Parties force Zuma to back down on Bills

Sowetan 12/6/97

(96)

Health Minister will now take three Bills back to Cabinet following stiff opposition

By Rafiq Rohan
Political Correspondents

HEALTH Minister Dr Nkosazana Zuma has backed down and withdrawn her controversial health Bills with all minority parties declaring her move as a victory for democracy.

Late last week all opposition parties in Parliament walked out of the portfolio committee on health meeting.

They accused the African National Congress of trying to push through new legislation that would restrict doctors' rights to dispense medicines and would introduce a mandatory two-year vocational training period for medical students.

The proposed changes have resulted in countrywide protests by medical students and doctors.

Before making the announcement yesterday, Zuma made an impassioned speech, insisting that her only intention was to ensure that South Africans received "affordable, quality and safe medicines".

However, the Pharmacy Amendment Bill, the Medicines and Related Substances Control Amendment Bill and the Medical, Dental and Supplementary Health Service Professions Amendment Bill have not been scrapped.

Zuma said she would resubmit the Bills to Cabinet next Wednesday.

"I would like to study the submissions and make sure that the genuine concerns and suggestions are taken on board," she said.

The Pan Africanist Congress' Ms Patricia de Lille welcomed Zuma's announcement to look at the Bills again and ascribed it to the "joint mass action" of the opposition parties.

The African Christian Democratic Party's the Reverend Kenneth Meshoe said: "We welcome the minister for doing the right thing by listening to minority voices."

ANC chairman of the portfolio committee Dr Abe Nkomo saluted Zuma for taking the Bills back to Cabinet but described the behaviour of certain parties as "sad and shocking".

The Democratic Party's Mr Mike Ellis thanked Zuma for "finally seeing reason" but slammed her for her "blatant disregard for any viewpoint but her own (which) completely undermined the public participation process and generated intense dissatisfaction in both the public and private sectors".

'RAPPED OVER KNUCKLES'

Zuma withdraws three bills

CT 12/6/97

NKOSAZANA ZUMA appears to have been "rapped over the knuckles" for not following the proper processes in preparing health legislation for Parliament. Health Writer **CAROL CAMPBELL** reports.

HEALTH Minister Dr Nkosazana Zuma has withdrawn three highly controversial health bills — which would have changed the face of South African medicine — from Parliament.

She will resubmit the amended legislation to the cabinet next Wednesday, but the whole process of public consultation over the country's new health laws will begin from scratch.

The withdrawn bills are:

- The Medical, Dental and Supplementary Health Services Professions Bill — this would have forced medical students to do an extra two years of vocational training in rural areas before they finally graduated.
- The Medicines and Related Substances Amendment Bill — this enabled Zuma to import cheap medicine for use in public hospitals and encouraged the sale of generic medicines. It was unpopular with the pharmaceutical industry but welcomed by medical aid companies.
- The Pharmacy Amendment Bill — this would have led to the deregulation of pharmacies so businessmen and not only pharmacists could own a pharmacy. The intention was to get pharmacy services into rural areas and townships.

Last night sources in Parliament said they believed the cabinet had "rapped Zuma over the knuckles" for not following the proper processes while preparing the legislation for Parliament.

"Why else would this have been slowed down at the last minute?"

PRESSURED: Health Minister Nkosazana Zuma

Public hearings on the three bills were held last Friday and Monday but were dismissed as "a farce" by opposition parties who said the legislation was being rushed by the African National Congress government.

They were supported by many of the organisations giving evidence at the hearings who complained that 10 minutes to present their side of the story on such fundamental legislation was inadequate.

Committee members were not given the opportunity to ask questions on two of the bills because of time constraints.

Democratic Party spokesman Mr Mike Ellis, the most vocal opponent of the rushing through of the legislation, said Zuma's surprise move was a "victory" for the Democratic Party and proved that "democracy is not dead" in South Africa.

"We thank the minister for at last seeing reason," he said.

Last night medical students at the University of Cape Town said they were "elated" that the idea of adding two years to their training (pushing it to nine years) was going to be reconsidered.

Dr Mark Sonderup, vice-chairman of the Junior Doctors' Association, said he was "encouraged" but "cautiously optimistic" by the surprise move.

"We are dealing with a minister who has quite a track record. I say let's wait and see."

Undergraduates also tempered their relief with caution, but felt students would be given more of an opportunity to state their views the next time around.

Most said they were, in principle, not against having to perform vocational training — a term some also had a problem with — but were opposed to Zuma forcing it on them.

"I don't think anybody was objecting to the idea behind vocational training — we're all dedicated to health care in this country," said third-year student Mr Michael Huth.

But he added: "(Zuma's) got good ideas but bad methods. The way she wanted to do it would have been detrimental, not beneficial."

He called on Zuma to consult widely with students, saying: "She can't just make unilateral decisions."

Second-year student Mr Tilman Stasch agreed: "Now we hope she is going to look into our arguments."

A "relieved" fifth-year student, who did not want to be named, said the impending vocational training period had "affected people's lives drastically".

❑ Turn to Page 3

Zuma withdraws health bills

❑ From Page 1

(96)

She, and many of her fellow students, would have been "very tempted" to leave the country because of the compulsory training.

CT 12/6/97

"At least now ... they (health authorities) will have to take us more seriously," she said.

However, the student said she "wouldn't be surprised" if vocational training was introduced anyway.

Fellow fifth-year student Mr James Drew said he was "just happy it (the law-making process) will be done in the proper way".

"If they (authorities) go about it the right way, then it can be worked out," he said.

Drew took issue with the term "vocational training", saying it was a "slap in the face" and implied doctors were inadequately trained "when everybody knows it's community service".

Mauritian Mr Mohammad Chumroo, a second-year student, said he had been considering settling in South Africa but had changed his mind over vocational training, which was "like the army".

Now he would reconsider — if the conditions were favourable, he said.

"I'm happy about it," he said, and expressed the hope that students would be consulted.

Mrs Erica Mann, vice president of the Pharmaceutical Association of South Africa, said she was "thankful" and "grateful" that Zuma had stalled the passing of new legislation on medicines.

"My concern is that she has only promised a week for changes to the bill which I don't think is enough time to do everything properly."

Dr Hendrik Hanekom, secretary general of the Medical Association of South Africa (Masa), said he was pleased that Zuma had heeded the concerns and recommendations expressed during three days of public hearings.

"Masa will most certainly make

Zuma's withdrawal of three bills welcomed

Star 12/6/97 (96)

By Jovial Rantao and Janine Simon

Health Minister Dr Nkosazana Zuma's withdrawal of the three controversial medicines and pharmaceutical bills has elicited a cautious welcome.

Role players said dissatisfaction with the process of the public hearings was so deep, the minister ran the risk of being challenged in the Constitutional Court.

They question how the more than 200 submissions on the Pharmacy Amendment Bill, the Medicines and Related Substances Control Bill and the Medicine, Dental and Supplementary Health Service Profession Amendment Bill can be dealt with in just one month.

Zuma said in the National Assembly yesterday that she was withdrawing the bills to allow her department to go through concerns raised by all stakeholders, and would resubmit them to the Cabinet on July 18.

The new bills, containing the same principles, would then be subjected to public hearings and are expected to be tabled in Parliament in August.

"The bills will enable South Africans to access safe, effective medicines from the global market if local industry cannot give us a reasonable price," Zuma said.

The Junior Doctors Association of South Africa (Judasa), which has threatened legal action if the health services profession bill is pushed through, said they were cautiously optimistic that Zuma had realised the need to consult with all stakeholders. Chairman Dr Mangaliso Mhlaba said Judasa urged the minister to suspend the issue of vocational training for 1998.

Mirryena Deeb, chief executive of the Pharmaceutical Manufacturers Association, questioned whether 200 submissions could be considered, and the medicines bill redrafted within one week.

The Pharmaceutical Society of South Africa's executive director Ivan Kotze said most of the submissions were on technical points, and it was not impossible that decisions on the few important issues could be taken within a week.

NP MP Willie Odendaal said: "The NP would not have accepted the way in which parties were excluded from asking questions."

The DP's Mike Ellis said the withdrawal was a victory for the democratic process.

The SA Communist Party accused some parties of not promoting health care for all.

No major change to health bills — Zuma

(96)

CAPE TOWN — Health Minister Nkosazana Zuma said yesterday that the three contentious health bills she had withdrawn from Parliament would not undergo substantial changes and denied that she was bowing to pressure.

Zuma announced on Wednesday that she was withdrawing the Medicines and Related Substances Control Amendment Bill, which will allow parallel imports of cheaper medicines and regulate generic substitution as well as legislation to set up new pharmacy and health professions councils.

Zuma said she intended to study submissions made to recent parliamentary hearings on the measures and resubmit the bills to the cabinet next week.

She said yesterday the withdrawals were "just a normal democratic process when there's been a hearing.... People must not read anything into the withdrawal other than that I'm looking through the submissions and will incorporate some of the useful suggestions." — Sapa

BD 13/6/97

ANC pulls the plug on Zuma's embattled bills

'Goings-on behind scenes'

ARG 14/6/97 (96)

JEAN LE MAY
STAFF REPORTER

Health Minister Nkosazana Zuma has withdrawn three controversial bills under pressure from colleagues, including African National Congress MPs.

"It is common knowledge that Dr Zuma was told bluntly to withdraw the bills," said a source.

In spite of Dr Zuma's repeated statements that she would not budge on the intentions behind the bills, Saturday Argus has established from sources in Parliament that she withdrew the bills after pressure from within the Cabinet, from politicians (including African National Congress MPs) and from people with interests in health and pharmaceutical businesses.

The amended bills will now go to the Cabinet and the whole process of consultation and Parliamentary debate will start all over again.

Mike Ellis, Democratic Party spokesman on health, said yesterday that withdrawing the bills was "a most unusual process".

He said it was a sign that "something very serious was happening behind the scenes".

"Dr Zuma finally overstepped the mark by trying to keep total control, and by behaving in a way which was anything but democratic."

Mr Ellis said that one of the most serious objections to the Medical, Dental and Supplementary Health Service Professions Amendment Bill was that the minister was given the power to override the provisions of the existing act by the proposed amendments.

Nkosazana Zuma: backed down

Mr Ellis said anybody could now be made a health practitioner by the minister.

> ***'It is common knowledge that Dr Zuma was told to withdraw the bills'***

In its submission, the Interim National Medical and Dental Council said that if this became law "the act can, in essence, be done away with, since the minister, not Parliament, decides on the registration of practitioners".

The withdrawn bills are: the Medical, Dental and Supplementary Health Service Professions Amendment Bill; the Medicines and Related Substances Amendment Bill and the Pharmacy Amendment Bill.

Dr Zuma told Parliament that she was withdrawing the bills and would resubmit them in a week. In the meantime she would look at submissions to see "if there was anything that can be taken on board".

The bills were referred back to the SA Dental and Medical Council, the Medicines Control Council and the Pharmacy Control Council for comment.

The councils were given a week to respond.

Dr Zuma's autocratic approach to the issue was demonstrated by the manner in which she and her department ignored the formal written submission on the proposed amendments made by the Interim National Medical and Dental Council in July, 1996.

In a submission made on May 19 this year, the council said that it "received no feedback on its submission, nor was it at any stage requested for further input. In April, 1997 the council informally obtained a copy of a draft bill".

"Council noted that in broad terms its proposals had been incorporated. However, it was concerned that it was not approached for any input or comment prior to the publication of the draft bill," the council's submission said.

Zuma 'faced pressure from all sides to back down'

Star 14/6/97 (98)

By JEAN LE MAY

Health Minister Nkosazana Zuma has backed down in the row over three controversial health bills by making substantive changes to them.

In spite of Zuma's repeated statements that she would not budge on the intentions behind the bills, our sister paper, *Saturday Argus,* has established from sources in Parliament that she withdrew the bills after pressure from within the Cabinet, from politicians (including ANC MPs) and from people with interests in the health and pharmaceutical businesses.

"It is common knowledge that Dr Zuma was told bluntly to withdraw the bills," said a source. The amended bills will now go to the Cabinet, and the whole process of consultation and parliamentary debate will start again.

Mike Ellis, Democratic Party spokesman on health, said yesterday that withdrawing the bills was "a most unusual process". It was a sign that "something very serious was happening behind the scenes", he said.

"Dr Zuma finally overstepped the mark by trying to keep total control, and by behaving in a way which was anything but democratic."

Ellis said one of most serious objections to the bill on medical, dental and supplementary health service professions was that the minister would have been given the power to override the registration provisions of the act. The effect of this was that anybody could become a health practitioner if the minister agreed.

In its submission, the Interim National Medical and Dental Council said that if this bill became law, "the act can, in essence, be done away with, since the minister, not Parliament, decides on the registration of practitioners".

The withdrawn bills are the Medical, Dental and Supplementary Health Service Professions Amendment Bill, the Medicines and Related Substances Amendment Bill, and the Pharmacy Amendment Bill. Zuma told Parliament she was withdrawing the bills and would resubmit them in a week's time. In the meantime she would look at submissions to see "if there was anything that can be taken on board".

The bills were referred back to the Interim National Medical and Dental Council, the Medicines Control Council and the Pharmacy Control Council for comment. The councils were given a week to respond.

In a joint statement, the African Christian Democratic Party, the DP, the IFP, the NP and the PAC called for fresh hearings on the amended version of the Pharmacy Amendment Bill.

Zuma's autocratic approach to the issue was demonstrated by the manner in which she and her department ignored the formal written submission on the proposed amendments made by the Interim National Medical and Dental Council in July 1996.

In a submission made on May 19 this year, the council said it had "received no feedback on its submission, nor was it at any stage requested for further input ... in April 1997, council informally obtained a copy of a draft bill ... Council noted that in broad terms its proposals had been incorporated. However, it expressed its concern that it was not approached for any input or comment prior to the publication of the draft bill."

Apart from its objections to the overriding power given to the minister, the council had other criticisms. These included:

- Proposals that regulations may be made by the minister "in consultation with the council" instead of "on the recommendations of the council". This abrogated the concept of the council as an independent body, the council claimed.
- The proposed increase from one to nine of the number of people representing the provin es on the council. This was "totally ex essive" and would place a fu ther bur n on the professions in fr a 49-r mber council.

Sunday Times Business Times
June 15 1997

Zuma's retreat is strictly temporary

(96) (96)

THE temporary withdrawal of Health Minister Nkosazana Zuma's controversial trio of health Bills should not be seen as a retreat from restructuring the health care industry.

The Bills are already being redrafted, and they will be placed before the cabinet for approval on Wednesday. The ministry has a good idea of what it wants to amend.

The Bills deal with how medicines reach the market, aiming eventually to make them cheaper. A pharmacy Bill provides that people other than pharmacists will be able to own pharmacies, and another Bill provides for extended vocational training by doctors.

Opposition to the Bills reached a peak this week with threats of investment pull-outs by multinational companies and court action. Zuma has said the philosophy and framework behind the Bills will remain intact, although she will try to take into account the many submissions on the Bills where it seems necessary.

Among the contentious areas likely to be addressed are parallel imports of drugs. The government is not likely to give the multinational drug companies as much ground as they want. However, it will tighten up the section on the circumstances under which imported drugs will be registered by the drug authorities.

This section also worried the Medicines Control Council, which wants to be able to reassure the public that drugs available in South Africa are safe and effective.

The international trade lobby which vigorously opposed the Bills may have found a willing ear in some of Zuma's cabinet colleagues, such as Trade and Industry Minister Alec Irwin or Finance Minister Trevor Manual.

Opposition to vocational training is profound and may in the end cause more trouble than the exercise was worth.

ST (BT) 15/6/97

Medical schemes' body threatens to go it alone on importing of drugs

Star 16/6/97 (96)

By Craig Urquhart

As the Ministry of Health continues to stall over the controversial Medicines and Related Substances Control Amendment Bill, the Representative Association of Medical Schemes (Rams) is threatening to "go it alone" and establish its own guidelines for the parallel importation of drugs.

"We will explore every avenue to obtain cheaper medicine, including the parallel importation of drugs. We refuse to be held hostage to the current structure and we will support any measures by the Government, including these bills, to obtain cheaper medicines," said Rams director of policy Dr Aslam Dasoo.

The move from the multi-billion-rand organisation, which represents 186 private medical schemes that provide health cover to 15% of South Africans, could set the standards to which the Government would ultimately have to adhere.

"The outcome of the bill does not stop private schemes from slashing the cost of available drugs as long as they are submitted to the Medicines Control Council. We're advancing the Government's intended programme because it makes good financial sense," said Dasoo.

Rams, which is facing pressures from its members because of their soaring contributions, says some schemes face bankruptcy if generic substitutions are not legalised.

Bowing to pressure from US politicians and business, the Government last week withdrew the proposed bill which would mandate that physicians prescribe only generic drugs.

SA prices are among the highest in the world

Health Minister Dr Nkosazana Zuma said she was confident the bills would be passed with minor adjustments.

She said the price of medicine in South Africa was among the highest in the world and the provision of safe, effective and affordable drugs in the right quantities to the whole population was a national priority.

She plans to import cheap medicines from overseas for use in public hospitals and clinics – a practice which is common in Europe and Africa – and legalise generic substitution.

This means that pharmacists will have to offer patients cheaper medicines as an alternative to medicines prescribed by their doctor. If doctors do not want an alternative, they will have to write this on the patient's prescription by hand.

The National Convention of Dispensing Doctors said doctors would fight in court if necessary for their constitutional right to dispense medicines. It says doctors are also questioning the safety of generic substitution and whether nurses and pharmacists should be permitted to prescribe drugs – which is recommended in the bill.

Pharmaceutical Society of SA executive director Ivan Kotze said most of the submissions were on technical points, and it was not impossible that decisions on the few important issues could be taken within a week.

Bitter fee war erupts between pharmacies and medical aids

(96)

Chemists to charge R20,90 per prescription

ARG 17/6/97

ARGUS CORRESPONDENT

Johannesburg – A bitter war between the pharmaceutical and medical aid industries over price reform is set to hit medical aid members in their pockets.

The fight centres on the introduction of a professional fee for pharmacists, a key component of the national drug policy to be introduced if the controversial Medicines and Related Substances Control Amendment Bill is passed.

The concept is to replace the complicated system of profit mark-ups in the wholesale/retail pharmaceutical industry with a flat wholesaler mark-up and dispensing fee per product, to be phased in from June 26.

This week giant medical aid administrator Medscheme said it was being "held to ransom" over the issue of dispensing fees by United South African Pharmacies, which represents 1 480 of South Africa's 2 900 community pharmacies.

Medscheme spokesman Lorraine Tulleken said the medical aids had been notified that USAP intended implementing a R20,90 dispensing fee and would boycott those schemes refusing to accept the new pricing structure by withdrawing credit to schemes and asking their clients to pay cash for their medicines.

The impact of USAP's demand, evaluated as part of a survey of 10-million prescriptions across 32 medical aids, revealed that on average the cost of medicines would rise by 17%, Ms Tulleken said.

But Keith Johnson, head of the pricing committee of the Pharmaceutical Society of SA, said Medscheme's figures were debatable and had not been revealed to the other two organisations that had analysed price impact, the PSSA and Representative Association of Medical Schemes.

"I question their motives. The new structure will improve overall costs in the long-term and it is strange that they have done this," said Johnson.

Medscheme emphasised that the poor would be hardest hit by the fee which increases the costs of lower-priced drugs.

Furore over pharmacists' dispensing fee

BD 17/6/97 (96)

Stephané Bothma

A SHOWDOWN is looming between medical aid schemes and half the pharmacies in SA which plan to introduce a dispensing fee that could result in patients having to pay cash for prescription medicines.

The dispensing fee, of R20,90, would result in an average increase of 17% in the cost of medicines, the Medscheme Group said yesterday.

It said United SA Pharmaceuticals, representing 1 480 of SA's 2 900 pharmacies, had informed medical aid schemes of an intention to implement a R20,90 dispensing fee from June 26.

The pharmacies threatened to boycott medical schemes refusing to accept the pricing structure by making patients pay for medicines in cash.

"To avoid the boycott would mean an average increase of 17% in the cost of medicines and hardest hit would be those in the lower income bracket," a Medscheme spokesman said.

United SA Pharmaceuticals said the dispensing fee was being introduced in an effort "to reduce the high price of inflation".

The move by the pharmacies was evaluated as part of an audited survey of 10-million prescription items across 32 medical aids commissioned by Pharmaceutical Benefit Management (PBM). Findings showed that, on average, the dispensing fee would increase medicine costs 17%. "In the case of schemes for lower-income workers, the increase would be between 20% and 26%," PBM MD John Cowlin said.

He said the feasibility study indicated that the dispensing fee could often be higher than the actual cost of the medicines.

Bafana Nkosi, principal officer of Bonitas Medical Fund, which serves 500 000 black South Africans, said the threatened boycott was discriminatory. "Few of our members will have the cash and we object to being blackmailed into paying more for medicines when members get no added value for these high costs."

In SA by far the largest proportion of money paid out on medical aid benefits was for medicines — about 32% compared with an average of 12% in the UK and 14% in Zimbabwe.

"One of the key aspects of containing the health care cost spiral in this country in recent years has been the management of medicines, especially those for chronic illnesses," the Medscheme spokesman said. Medical aid schemes, generally, believed a negotiated solution was necessary for health care to be affordable, she said.

Cosatu said it was confident that Health Minister Nkosazana Zuma would remain firm to the commitment that government would put in place mechanisms which would lead to a reduction in the cost of essential medicines despite the "enormous bullying tactics used by companies who stand to see a cut in their super profits".

Referring to Zuma's move last week of temporarily withdrawing three controversial health bills from Parliament, Cosatu "strongly urged" the African National Congress and the cabinet to support Zuma's intention to reintroduce speedily the proposed legislation after it had been refined on the basis of inputs from the public.

Drug prices set to spiral in pharmacy row

Star 17/6/97 (96)

Patients will be forced to pay cash for prescription medicines unless their medical aids agree to a R20.90 dispensing fee

By Janine Simon

A bitter war between the pharmaceutical and medical aid industries over price reform is set to hit medical aid members in their pockets.

The fight centres on the introduction of a professional fee for pharmacists, a key component of the national drug policy which can be legislated if the controversial Medicines and Related Substances Control Amendment Bill is passed.

The concept is to replace the complicated system of profit mark-ups in the wholesale-retail pharmaceutical industry with a flat wholesaler mark-up and dispensing fee per product. It is due to be phased in from June 26.

This week giant medical aid administrator Medscheme said it was being "held to ransom" over the issue of dispensing fees by the United South African Pharmacies (USAP), which represents 1 480 of South Africa's 2 900 community pharmacies.

Medscheme spokesman Lorraine Tulleken said the medical aids had been notified that USAP intended implementing a R20,90 dispensing fee and would boycott those schemes refusing to accept the new pricing structure by withdrawing credit to schemes and asking patients to pay cash for medicines.

The impact of USAP's demand, evaluated as part of a survey of 10-million prescriptions across 32 medical aids, revealed that on average the cost of medicines would rise by 17%, Tulleken said.

The survey was commissioned by Pharmaceutical Benefit Management, the company which processes drug claims for Medscheme.

Bonitas medical fund principal officer Bafana Nkosi said USAP's threatened boycott was discriminatory and few members would be able to pay cash.

But Keith Johnson, who heads the pricing committee of the Pharmaceutical Society of South Africa, said Medscheme's figures were open to debate and had not been revealed to either of the other two organisations that had done in-depth analysis of price impact.

These were the PSSA and Representative Association of Medical Schemes (RAMS).

"I question their motives. The new structure will improve overall costs in the long-term and it is strange that they have done this," said Johnson. "No other pharmaceutical benefit management has shown the same kind of potential increase in costs."

However, Medscheme emphasised that the poor would be hardest hit by the fee which increases the costs of lower priced drugs.

RAMS policy director Dr Aslam Dasoo said it was impossible to assess the impact of the new fee as final pricing lists were still being collated.

Dasoo said the problematic area was determining the true cost of drugs when they left the manufacturer as they were sold at different prices to different parties in retail.

"The price impact will be greater if manufacturers come on board and reveal their prices. But there will be a favourable impact nonetheless," said Dasoo.

RAMS has a mandate from all its member schemes to push ahead with introducing the new fee structure.

Medicines to be sold at cost plus a fee

BD 18/6/97 (96)

Stephané Bothma

PRESCRIPTION medicines would be sold by most of SA's 2 750 pharmacies at cost price plus a fee of R17,10 from July 28, United SA Pharmacies chairman Julian Solomon said yesterday.

Providing details of the fee, originally to have been R20,90, Solomon said the profits of some medical aid schemes and administrators would decline by millions because of the pricing structure, which was in line with government's national drug policy.

Although some medical aid schemes claimed the fee would result in an average increase of 17% in the cost of medicines, he said the cost of expensive prescription drugs would be significantly reduced.

"The object of this professional fee is to move the incentive for pharmacists from making a small profit on the sale of medicines to being rewarded for their professional services.

"This will dramatically bring down the total cost of the medicine drug bill," he said.

The move by United SA Pharmacies, which represents 1 553 pharmacies in SA, has hit strong opposition from medical aid schemes or administrators which stand to lose discounts of up to 30% on the cost of medicines.

Negotiations between pharmacies and medical aid schemes over the past nine months to resolve the issue had been unsuccessful, Solomon said.

"Medical aid schemes have been

Continued on Page 2

Medicines

(96)

Continued from Page 1

BD 18/6/97

bleeding pharmacies to the extent that around 100 a year are forced to close."

He said United SA Pharmacies members would charge the fee from July 28, but in some cases from June 26. Nonmembers were likely to follow.

Members of medical aid schemes which refused to accept the pricing structure would have to pay pharmacists for their prescription drugs from those dates and then submit claims to the schemes, Solomon said.

The introduction of the fee was in line with a decision by drug wholesalers to sell goods at cost to pharmacies from July 28. It replaces the practice of adding a profit margin to the cost, offset by a discount passed onto medical aid schemes by pharmacists.

Solomon said the principle of a professional fee had been endorsed by the SA Pharmacy Council and the Representative Association of Medical Schemes, and formed part of government's national drug policy.

"When all parts of the drug policy are in place the end price, across the board, will be substantially lower in total than is currently the case.

"Whether the cost of a prescription is R50 or R500, the professional fee remains R17,10," he said.

The fee would be used to cover the cost of running pharmacies, and included VAT.

Medical aid schemes earlier said an audited survey of 10-million prescription items showed that, on average, the dispensing fee would increase medicine costs 17%.

Solomon said this was misleading, as the new lower cost of medicines had not been taken into account.

Sapa reports a redrafted version of controversial legislation aimed at lowering the price of drugs is expected to be approved by the cabinet today.

'he good, bad and downright ugly of proposed medicines legislation

Star 18/6/97 (96)

issent over process, undue ministerial powers and the most commerly controversial clauses of new medicines legislation obscured support for other ts provisions.

The "good" in the Medicines Related Substances Con- Amendment Bill, the Phar- y Amendment Bill and the lical Dental and Supple- itary Health Service Profes- is Bill includes:

Clauses to wipe out incentives, rebates and free samples, often given by manufacturers to induce doctors, pharmacists and wholesalers to buy branded drugs, and regarded as perverse incentives;

■ Opening pharmacy ownership to, for example, chain stores and medical aid administrators. The Pharmaceutical Manufacturers' Association have been calling for this for years, saying bulk buying will drop prices by as much as 30%. The Representative Association of Medical Schemes (RAMS) believes medical schemes would be the only lay owners of pharmacies who would not be driven by profit;

■ Transparent pricing and single exit prices to be enforced by a new statutory pricing committee. This would forbid manufacturers altering prices for different buyers.

The "bad" is the wording of the terms on generic substitution and parallel importing, and fast tracking registration. The bill says:

■ A pharmacist shall inform the patient and substitute every script for a branded product with a cheaper generic, unless the doctor or patient forbids it in writing. Critics say this intrudes on the doctor/patient relationship; advocates say it empowers the patient.

■ Medicines identical to those registered in South Africa can be imported without further registration. Critics say this paves the way for fake medication; advocates say objections are based on protecting trade marks. If medications are properly assessed, finding cheaper sources overseas is good news. The same applies to the clause allowing the council to fast track registration of drugs deemed essential to national health.

"Downright ugly", say manufacturers, is a clause forcing firms to use international non-proprietary names instead of patented trade names in state tenders. This would nullify intellectual property rights and discredit the country in its search for international investment, and pave the way for counterfeiting, says the National Association of Pharmaceutical Manufacturers.

Most disturbing of all is the proposed power of the minister to override or sidestep the Medicines Control Council, as a cheap drug without proper independent evaluation can be called neither safe nor effective.

The seven main objectives

These are the main objectives of the National Drug Policy:

■ to ensure drugs reaching patients are safe, effective and meet approved specifications;

■ to promote availability of safe, effective drugs at the lowest possible cost;

■ to promote rational choice of drugs to be used in South Africa, according to the concept of essential drugs;

■ to ensure an adequate supply of effective and safe drugs;

■ to promote rational prescribing by both medical and pharmaceutical personnel;

■ to develop expertise and human resources to implement the policy;

■ to promote research to facilitate implementation and proper monitoring.

Medical aid schemes to fight threatened pharmacy boycott

Star 18/6/97 (96)

By Priscilla Singh
Health Reporter

The Representative Association of Medical Schemes (RAMS), an umbrella body representing medical aid schemes across the country, said yesterday it would not accept or approve any increase in the cost of medicines in spite of pharmacies' threats to boycott medical aid members unless they paid cash for their prescribed medicine.

RAMS was reacting to a threatened boycott by the country's largest group of pharmacies, United SA Pharmaceuticals, against medical aid members belonging to schemes that did not accept the R20,90 "professional fee" to be phased in from June 26.

RAMS executive director Declan Brennan said the threat to boycott medical aid scheme members was taking unfair advantage of the sick and lower-paid workers who could not afford to pay cash.

The threatened boycott follows the introduction of a professional fee for pharmacists, which is a key component of the national drug policy which will become law if the controversial Medicines and Related Substances Control Amendment Bill is passed.

The bill is expected to be approved by Cabinet today, according to health director-general Dr Olive Shisana.

Lower income consumers will be hardest hit once the new pricing structure is phased in and avoiding the boycott would mean an average increase of 17% in the cost of medicines.

▶ Pain in the pocket
Page 15

Zuma's revised bills before cabinet again

CT 18/6/97

(96)

CAROL CAMPBELL
HEALTH WRITER

THE cabinet meets today to discuss the three controversial health bills that were withdrawn unexpectedly by Health Minister Dr Nkosazana Zuma last week.

Zuma withdrew the legislation after two days of public hearings in Cape Town in which major players in the pharmaceutical industry, pharmacists and medical students vociferously protested that she was "rushing" public input into laws that would change the face of South African medicine.

The amended bills were handed back to the cabinet on Friday prompting speculation that the changes were "purely technical".

WILL CONSULT: Nkosazana Zuma

But Zuma is believed to have reworded the sections that would have given her power over the Medicines Control Council, the Pharmacy Council and the Interim Medical and Dental Council (soon to be called the Health Professions Council).

The old wording gave the minister the final say in all decisions relating to health, but the new wording should say she will only be able to make decisions "in consultation with" these councils.

Medical students probably still face two years of "community service" before they graduate, but yesterday the director general of health, Dr Olive Shisana, said they would know "very soon" what would be expected of them in future.

"I cannot give you details of the changes until the cabinet has seen the legislation," she said.

Zuma also stressed, when she withdrew the bills, that the principleswould not change.

If the cabinet is happy with the revamped bills they will be tabled in Parliament tomorrow.

But even if the bills are dealt with quickly they will be put on the back-burner until August because Parliament goes into a six-week recess on Friday.

The bills which were withdrawn by Zuma in a surprise move last week are:

- The Medicines and Related Substances Amendment Bill, which will enable Zuma to import cheap medicine for use in public hospitals and encourages the use of generic medicines.
- The Pharmacy Amendment Bill, which will lead to the deregulation of pharmacies so that businessmen can provide pharmacy services into rural areas.
- The Medical, Dental and Supplementary Health Services Professions Bill, which could force medical students to do two years of community service.

MINISTERS DIFFER ON DOCTORS' TRAINING

Bengu's challenge to Zuma

CT 16/9/97

NKOSAZANA Zuma's three controversial health bills are believed to have been given the thumbs up by cabinet yesterday and are scheduled to be tabled in Parliament today before the five-week recess. Health Writer **CAROL CAMPBELL** reports.

EDUCATION Minister Dr Sibusiso Bengu posed a challenge to his ANC colleague, Health Minister Dr Nkosazana Zuma, yesterday when he spoke out against adding extra years to a student's education for "vocational training".

Extra years on a degree would not improve the quality of a qualification, but instead the course curriculum had to be updated and improved to meet the needs of the new South Africa, he said.

By voicing his disapproval Bengu undermined a drive by Zuma to extend the training of medical students by two years so that they could work for the state in understaffed clinics and hospitals in rural areas and townships. Bengu's sentiments are believed to represent a growing feeling in the ANC on the issue.

"The position of the education department is clear and well known. If there is a problem, and the quality of students needs to be improved, then change the learning methods and programmes. I don't think an extension of the course is a viable option," he said.

He said he would discuss the issue in greater depth at yesterday's cabinet meeting. Three controversial health bills, withdrawn from Parliament by Zuma last week, were due to be discussed by the cabinet in the meeting.

One of the three was the Medical, Dental and Supplementary Health Services Professions Bill, which suggests that medical students do two extra years of community service/vocational training. This means a doctors' training could last as long as nine years.

Zuma withdrew the proposed legislation last week after a public outcry that she was rushing fundamental changes to health care.

At the time she said the main principles of the legislation would not change.

Now the question of which ministers' opinion will hold sway is waiting to be answered.

Do medical schools report to Zuma, whose department funds academic hospitals, or Bengu whose department funds universities?

Mr Lincoln Mali, a spokesman for Bengu said it was a "joint effort".

But Bengu's low opinion of "extended" vocational training is understood to represent a growing feeling in the ANC, that adding to a university course to force students into rural areas and the townships, will not resolve the skills shortage in these areas.

Rather the existing higher education courses, for all professions, like law, engineering, accounting, architecture have to be restructured to include vocational training in disadvantaged communities. The length of the courses though would remain unchanged.

The immediate problem facing Zuma, if she pushes ahead with her plan to make doctors "study" for another two years before qualifying, will be the shortage of trainers in far-flung areas.

There is talk that general practitioners living in areas like Eshowe, Queenstown or Mogwase will be asked to spend a certain number of hours every day supervising trainee doctors doing their vocational training in the area.

Also, residential facilities for medical students in many of these towns do not exist and will have to be built or upgraded at great cost to the state.

Medical students will have to be paid — probably on the same salary as a medical officer, which is about R100 000 a year.

Zuma's three controversial bills (one dealing with medicines, another with pharmacies and the third with medical professions) are believed to have been given the thumbs up by cabinet yesterday.

They are scheduled to be tabled in Parliament today before the five-week recess so that public hearings on the new legislation can be held when Parliament is back.

Zuma will announce to the public today exactly what her plans for the legislation entail.

Pharmacists 'living on the edge' over imminent changes

(96) Star 19/6/97

By Priscilla Singh
Health Reporter

Pharmacists are stressed out over the uncertainty of new dispensing regulations, a survey conducted by Roche Consumer Health has revealed.

Berocca Stress Barometer's high-stress findings showed only 18,4% of dispensing pharmacists had stress levels in the 30 to 40 category, which indicated they were coping with the repeated postponements and lack of clarity on new dispensing fees.

One pharmacist said the stress levels were an indication of the state of flux that the industry was in and that pharmacists were worried and confused about the variety of pricing structures proposed by the various controlling bodies and associations.

A professional fee is to be introduced for pharmacists once the controversial Medicines and Related Substances Control Bill is passed.

The bill was expected to be approved by Cabinet yesterday.

Other factors which contributed to the high-stress levels among pharmacists was the fact that medical aids were at odds about the dispensing tariffs.

Staff are feeling vulnerable

Survey co-ordinator Gill Polglase said: "The environment for the dispensing pharmacist is now changing drastically and until all the kinks are ironed out, the stress levels will run high."

A startling finding by the stress barometer showed that 26% of pharmacists had very low-stress levels, between 0 and 20, and was a possible indication that their circumstances had finally got the better of them.

Polglase said this category was generally very laid back, distracted and lacked motivation.

At least 38,47% had scores higher than 40 and some 19% had a stress level over 50.

The pharmacists in general said that the future was very uncertain in their environment.

They said pharmacies would have to streamline their operations to make ends meet.

This would possibly lead to retrenchments and staff at smaller pharmacies, which felt the most threatened by the imminent changes, according to the survey.

Zuma opens way for supermarket drugs

(96) (~~[illegible]~~)

Cabinet approves health bills which will go before Assembly: store pharmacies must be run by fully qualified staff

STAFF REPORTERS Star 20/6/97

Supermarket chains and other businesses will be allowed to run pharmacies in their stores, in terms of revised health bills approved by the Cabinet yesterday.

The three bills represent Health Minister Nkosazana Zuma's controversial efforts to bring down the cost of health care and make it more accessible.

After Cabinet approval, they must now be passed by Parliament's National Assembly before becoming law.

The move to remove the monopoly ownership in the pharmacy retail industry – at the moment only pharmacists may own pharmacies – has been welcomed by major medical scheme Medscheme. In terms of the new legislation businesses may own pharmacies, provided they are run by qualified personnel.

Ivan Kotze, executive director of the Pharmaceutical Society of South Africa, said he welcomed the introduction of a pricing committee which would set the price of drugs and ensure that the smaller pharmacies, which did not have the financial muscle to negotiate discounts, would not be put out of business.

Barney Sachs, national director of the National Association of Pharmaceutical Wholesalers, said he did not think that the bill would lead to increased use of medicines. The changes, which would allow non-pharmacists to sell drugs, would mean that more people, especially in the rural areas which formerly did not benefit from having neighbourhood pharmacists, would have access to quality medicines.

He said he did not feel that the smaller pharmacist would be jeopardised by the changes, especially as pharmacists were becoming more patient-oriented rather than product-oriented.

The bills also provide for newly-qualified doctors being compelled to do two years' community service.

Zuma said she had to decide how the notion of community service would fit in with the two years' vocational training for doctors provided for in the bill. The Interim Medical and Dental Council said interns needed a period of supervised, practical training to prepare them for independent practice.

"The council's standpoint is that a period of vocational training should be required." This would be in the best interests of newly-qualified doctors as well as the public, the council had said.

The Medical Association of South Africa said it was "surprised and disappointed" that Zuma was proceeding with the legislation. The matter would be discussed at Masa's annual federal council, which begins in Pretoria today.

(96)

PHARMACISTS & MEDICAL SCHEMES

FM 20/6/97

Court threat in pharmacy fight

Dispensing fee could cost more than the medicine

Medical schemes are considering legal action to halt a boycott planned by half the pharmacies in SA over the industry's refusal to accept the introduction of a R20 dispensing fee for pharmacists.

Medscheme spokesman Gary Taylor says the fee will add R12m (17%) to its average monthly medicine bill. This could lead to higher medical aid premiums, higher employment costs and could even result in members quitting their schemes.

According to a feasibility study by Medscheme subsidiary Pharmaceutical Benefit Management (PBM) some lower-income schemes will experience price increases of up to 40% and members could find dispensing fees exceed the cost of medicine.

The Competition Board has been petitioned by some Medscheme members to halt the boycott planned by United SA Pharmaceuticals (USAP) on the grounds that it amounts to price collusion.

USAP claims to represent 1 553 pharmacies and is threatening to boycott all Medscheme's 57 member schemes from June 26, unless its pharmacists are granted a R20,90 dispensing fee per script item.

If the boycott goes ahead, Medscheme's 1,6m members will be forced to pay cash for medicine bought at these pharmacies and will then have to wait up to 60 days before being reimbursed by their schemes.

USAP chairman Julian Solomon claims the R20,90 fee will not increase medicine prices if Health Minister Nkosazana Zuma's plans to reduce medicine costs prevail.

In this context the move is about ensuring the survival of pharmacists who fear they will be put out of business by Zuma's plans which would allow retailers like Pick 'n Pay and Clicks to own pharmacies.

The Representative Association of Medical Schemes (Rams) — of which Medscheme is the largest member — began negotiations with the pharmacy sector, including USAP, over a dispensing fee last year. The deadline for its introduction is July 1 but there is still no agreement on the fee.

The idea expounded by Zuma's national drugs policy is to replace traditional markups of 50% by pharmacists with a dispensing fee of the same magnitude.

Claire Bisseker

CHEAPER MEDICINE

Noble objective pursued by dubious means

The Health Minister's retreat over three health Bills is a victory for a civil society which lobbied against what it saw as a bid to railroad them through parliament

FM 20/6/97 (96)

Nkosazana Zuma deserves credit for being the first Health Minister with the political will to tackle the powerful vested interests of the pharmaceutical industry and medical establishment head on.

Medical schemes say her bold plans to allow parallel imports of cheaper medicine from other countries will save them billions of rand. Health economists back her proposal to cut medicine costs by allowing the lay ownership of pharmacies — a recommendation issued repeatedly, from the Browne report in 1985 to the Broomberg/Shisana report last year.

But Zuma's failure to consult professional councils and her lack of insight into the profession and technical aspects of medicine safety have posed dangers of their own.

Though society lauds Zuma's intention to lower the unacceptably high cost of medicine, her methods have been criticised.

Parliament's health portfolio committee has heard evidence that the Medicines & Related Substances Amendment Bill will violate SA's obligations under international trade agreements, precipitate legal action and disinvestment by infringing drug companies' intellectual property rights, open the door to counterfeit medicine and has enough technical errors to be unworkable.

These threats are too easily dismissed as a backlash by pharmaceutical manufacturers whose only concern is the bottom line.

One of the most vociferous critics has been the Medicines Control Council (MCC), which has urged the committee not to accept Zuma's plans for parallel imports of medicine.

If the Bill is passed without amendments, any importer will be allowed to buy a multinational's drugs outside its controlled distribution networks and take advantage of substantial differences in countries' drug prices.

Though parallel importing can mean cheaper drugs for users, the MCC warns that unless they come from the same manufacturing site as drugs already registered in SA or are subject to the same control procedures as other medicine, the door will be opened to counterfeit drugs.

Yet an international authority on counterfeiting was one of three international pharmaceutical representatives prevented from addressing the committee during the public hearings on the Bill. The reason given was that it represented organisations that do not have local subsidiaries — a shortcoming which has never prevented the department from calling on international experts to address the same committee.

Given the lengths to which the committee went to stifle proper debate, Zuma's withdrawal of the Bills is even more remarkable.

Thirty-four submissions were scheduled for one day, allowing the participants 10 minutes each and leaving no time for questions.

Submissions were made on the original Bills because revisions were not available. This prompted opposition parties to walk out in protest.

But why did Zuma, having brazened her way out of *Sarafina II* and the Virodene scandal without apologising, suddenly get cold feet over the Bills when she appeared to have the committee in her pocket?

The cynical response is that she has withdrawn the Bills as a sop to interest groups to give the appearance of having reviewed their concerns but will reintroduce the legislation to the Cabinet this week with a few minor changes.

Zuma's remarks on radio about pressing ahead with her plans have reinforced scepticism that the withdrawal may be a tactical retreat rather than a sign of willingness to reappraise the Bills.

Backbenchers say she has bowed to pressure from within the ANC, which was feeling the heat from international lobby groups with US backing. This, the threat of interminable law suits from the R10bn pharmaceutical industry and stirrings of mass action from medical students over compulsory vocational training may have forced her to reconsider.

Or perhaps this often intransigent Minister has geniunely decided to listen to critics this time. If so, it could be taken as a sign of moral strength, not weakness we will see.

Whatever her motive, she has not made much political capital out of her retraction. In fact, far from conceding to parliament she was withdrawing the Bills because they were flawed, she spent 10 minutes praising their virtues before stating that they were being retracted.

Embarrassing maybe, but normal fare for most ministers in parliamentary democracies. Minister Zuma is sitting on a raft of Bills which will fundamentally alter health care. For the most part, her goals are credible. But the way she achieves them matters greatly.

Everyone's still tight on Zuma's facelift

ST(BT) 22/6/97 (96)

Changes to the Health Minister's Bills have failed to quell the uproar, writes PAT SIDLEY

THE Department of Health has agreed to changes in the three drugs Bills withdrawn earlier this month but has retained a controversial clause which will allow her to override concerns of the Medicines Control Council.

This will allow Health Minister Nkosazana Zuma to veto MCC decisions on many aspects of the industry, including the registration of drugs, if she deems it to be in public interest.

She could, for example, have blocked MCC opposition to the registration of the controversial AIDS drug Virodene.

Virodene was concocted by three Pretoria entrepreneurs with inadequate medical knowledge and no proper scientific protocols. Although the active substance was known to be toxic, Zuma backed the venture and opposed the stance of the MCC, which would not allow the drug onto the market. According to law, the council, which is the public's watchdog on medicines, had the last word.

If the law had not stopped Zuma, however, AIDS patients may have been given Virodene despite inadequate research to back its claims.

The MCC's vice-chairman, Professor Peter Eagles, said the council hoped the minister could still be persuaded to change her mind.

Several other clauses which had originally been opposed by the medicines watchdog, have, however, been dropped or changed.

Most importantly, Zuma made some concession on the parallel importation of drugs into the country.

The clause in the Bill that caused controversy suggested that a drug, which is available in South Africa, but was imported because it is cheaper, need not go through an SA registration process.

At present all medicines available in this country have to be registered by the MCC. Under the amendments medicines imported from other countries and which have been registered abroad, will have the sites of manufacture visited and examined by the MCC. This situation will continue as before.

Zuma has also acceded to one of the demands of the multinational pharmaceutical companies.

The companies objected strongly to a clause that brand-name medicines sold to the public sector could not carry the brand name of the drug on the package. This clause has been dropped.

But the moves have not blunted the ire of the Pharmaceutical Manufacturers Association, which had hoped that both parallel imports and the backing for generic drug substitution would be terminated.

The PMA's director, Mirryena Deeb, told Reuter she feared the environment envisaged by the revised Bills would scare multinationals into moving away. While the companies may not take legal action against the Bills, she feared they would simply disinvest from the country.

Zuma also made some amendments to the Bill governing compulsory service for medical students. Over the past two weeks students have called for a scrapping or at least a phasing in of their compulsory two years' service.

But the changes to the Bill merely promise them a choice between community service and vocational training although the expected haggling process over this may in any case serve to delay the introduction of the two extra years of training.

Pharmacists may have been given some concessions under the changes to the Pharmacy Amendment Bill, but, as the fight this week over professional fees shows, they will continue to face pressure to lower drug prices.

The debate about the dispensing fee has overshadowed the real issue: whether the public will get drugs at lower prices. The answer is "certainly not" if you are a private patient using a medical aid and pharmacies to get your medicine.

The row appears to be over a R2 per item fee on prescriptions, over and above the cost of the drug. This amount is the difference between the approximately R17 and R19 dispensing fee which may be charged per item on a script. The amount is designed to ensure that pharmacists will not feel a dent in their pockets when the effects of Zuma's moves in the market come through.

The amount has been disputed by many constituencies, but the present public row is between Medscheme, which wants the lower amount charged for its members, and USAP, which represents most pharmacies and which would not like to see the pockets of its pharmacist members raided.

In theory, from next week people going into a pharmacy will be charged on the basis of the cost to the pharmacist of the drug, plus the professional fee and two other charges. One is a 5% mark-up on the cost price and the other is a R3 fixed fee.

The percentage mark-up fee will encourage some of the old abuses by giving an incentive to dispense the more expensive drugs. The professional fee should be added on only when a professional service has been rendered.

The claim of the medical schemes is that poorer members buying cheaper drugs will be made to suffer by the new stance of pharmacists.

Nobody is contesting, however, that pharmacists should be allowed to continue to earn what they have been earning.

Even within the Department of Health some "sensitivity" to the problem is being sought. Cutting pharmacists' margins, or forcing medical members to use certain outlets and not others, may put pharmacies out of business.

Because this means some communities may be deprived of the only pharmacies available in their areas, the development is being watched with growing concern in the Department of Health.

It is now possible that the department will seek to intervene and meet both parties to try and find a compromise.

The compromise will be between suiting the pockets of the medical scheme administrators and the pharmacists. Members who have had to suffer huge increases in the cost of medicines will have very little say in the issue. Prices of medicines rose 37% in 1990, 45% in 1992, 19% in 1993, and 14% in 1995. These figures are supplied by the Representative Association of Medical Schemes.

Pharmacies label adverts 'hysterical'

(96)

Chemists breaking ranks on boycott plan, says Medscheme

Star 24/6/97

By Priscilla Singh
Health Reporter

The United South African Pharmacies (USAP) has labelled an advertising campaign by a medical administrator as "inflammatory" and "hysterical".

The advert, placed by Medscheme, focused on the supposed boycott of medical aid members by USAP pharmacies if the members did not pay the R20,90 dispensing fee.

The fee was set by USAP chairman Julian Solomon, who claims to represent half of the country's 2 900 pharmacies.

"I find the entire campaign by Medscheme quite hysterical, inflammatory and not representative of the facts.

"If anything, we increased our membership by 50 last week and now stand at about 1 600," said Solomon.

Solomon added that the dispensing fee would be implemented on Thursday, but that USAP was open to negotiation. However, Medscheme said that pharmacists were breaking ranks on the planned "cash or nothing" boycott of medical aid members who refused to pay them a R20,90 dispensing fee for prescription medicines.

The Government's drug policy requires medical aid members to pay pharmacists a professional fee for prescribed medicines they dispense in view of abandoning the previous 50% mark-up of drugs.

Medscheme public affairs director Gary Taylor said a number of individual members of USAP had, since Friday, assured Medscheme that they would not enforce the threat, and although they wanted a better deal, they would not turn away a sick patient.

Solomon said if medical schemes agreed to cover the fee, USAP would conduct all transactions on a medical aid card.

NEWS

Pay upfront or do without – what new medicines structure means

Chemists to boycott non-participating aid schemes

(96)

ARG 24/6/97

ARGUS CORRESPONDENT

Durban – Pharmacies will boycott members belonging to medical aid schemes that do not accept a new pricing structure to be implemented this week – forcing thousands of users to pay upfront or do without medicine.

The new structure will, according to one source, hit almost a million people who can least afford it. It will introduce a professional fee replacing the old mark-up system, in line with the Health Department's National Drug Policy.

Medicine prices are currently also under scrutiny by the Representative Association of Medical Schemes (Rams) and the Pharmaceutical Society of South Africa.

A scale of benefits document will be published later this week. However, medical schemes believe the introduction of a professional fee will cause drug prices to rise – by as much as 17% for some schemes.

Chairman of the United South African Pharmacies (Usap), Julian Solomon, said the more than 1 500 members of Usap would "no longer be able to deal with Medscheme (the biggest administrator of medical aid schemes in the country) under present onerous conditions".

Mr Solomon said the administrator refused to consider any change in the status quo that could deprive medical aids of income.

The pharmaceutical society proposed a pricing structure that would consist of a five percent mark-up (to cover financing) a further R3 for running a practice (overheads) and a professional tariff of R150 per hour or R15 per script.

That is R18 plus five percent plus VAT or about R20,90 per item. Medscheme proposed a flat fee of between R14 and R15 while Rams recommended a professional fee of R19 per lined item on a script to a maximum of three items per script.

Rodney Cowlin of the Pharmaceutical Benefit Management said the new structure would have a detrimental affect on members belonging to low benefit schemes.

"Almost one million people who could least afford it will be adversely affected."

Last week Medscheme urged Health Minister Nkosazana Zuma to resubmit urgently the Pharmacy Amendment Bill. The bill would allow people other than pharmacists to own pharmacies.

"Once the monopoly of ownership has been removed, medical aids would be free to contract a wider range of providers and achieve cheaper distribution costs of their medicines."

The Pharmacy Amendment Bill, the Medicines and Related Substances Control Amendment Bill and the Medical, Dental and Supplementary Health Services Bill were resubmitted to Parliament last week.

Mr Solomon assured consumers that pharmacies would be open to negotiation with members to make alternative paying arrangements if they could not pay up immediately.

He said medical aid schemes were an administrative nightmare, but hoped they would "come to their senses" and resume negotiations.

Chemists delay introducing prescribing fee

(96) Star 26/6/97

By Priscilla Singh

A pharmacy dispensing fee, supposed to begin today, has been delayed pending talks which started yesterday between United South African Pharmacies and Medscheme.

Julian Solomon, chairman of United South African Pharmacies, said there could be a one-week embargo on the implementation of the R20,90 fee.

Keith Hollis, chairman of Medscheme, which administers 57 medical aids, said the two bodies held intensive discussions yesterday.

"The professional role of the pharmacist was recognised, as well as the need to remove perverse incentives currently operating in the medicine distribution chain.

"The need for cost containment by medical schemes was also recognised," said Hollis.

Pharmacist Matau Tsiki of the Bertrams Link Pharmacy said it would have been impossible to bring in the fee today anyway because they had not received new pricing structures for medicines. "We are still working on the old system."

The fee was introduced after the Government decided to drop the 50% markup on drug prices, resulting in patients paying only the cost of prescribed medicines and the dispensing fee.

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Public protector asks Zuma to substantiate medicine prices claims

(96) BD 17/7/97

Kevin O'Grady

PUBLIC Protector Selby Baqwa has asked Health Minister Nkosazana Zuma to substantiate statements she made on the cost of medicines and the use of generic medicines in SA in support of medicines control legislation.

Baqwa's spokesman, Tinus Schutte, confirmed yesterday that Zuma's office and the health department had been approached following a complaint by the Pharmaceutical Manufacturers' Association last month.

Association CE Mirryena Deeb said the complaint was lodged as a result of "intellectually dishonest" comparisons Zuma and her officials made between commercial and noncommercial drug prices, apparently to create the perception that SA drug manufacturers were responsible for unreasonably high medicine costs. "Such high costs would then serve as justification for the draconian measures which Dr Zuma tried to rush through Parliament last month," Deeb said.

The legislation — the Medicines and Related Substances Control Amendment Bill — was withdrawn following complaints from local and international drug producers but was resubmitted to the cabinet in amended form and approved soon afterwards.

The main aim of the legislation, expected to come before Parliament again next month, is to make medicines more affordable, but certain measures have prompted threats of legal action by manufacturers.

Deeb said the association took issue with statements by Zuma and health ministry officials ahead of the legislation's introduction and believed they could not be substantiated. The statements included claims that SA medicine prices were among the world's five most expensive, that some medicines cost 4 000% more in SA than the world average and that medicine costs had increased at double the inflation rate during the past 10 years.

The association also objected to a statement that prescription of generic medicine in SA, at 16% of the total, lagged behind countries such as the US (48%) and Britain (54%).

Deeb said she had asked Baqwa to decide whether the statements and the reliance on the data on which they were based constituted improper conduct as the public had a constitutional right to accurate information.

The association had asked that Baqwa, in his report on the complaint, dispel the perception created by the statements that pharmaceutical manufacturers were "fat cats who profiteer and have no regard for the patients using the products sold by them".

Medicine costs: Zuma must answer Protector

By Themba Sepotokele

The Health Ministry was today still studying a document sent by the Public Protector Selby Baqwa, asking the Minister of Health, Nkosazana Zuma, to substantiate statements she has made relating to the high cost of local medicines.

This follows a complaint lodged by the Pharmaceutical Manufacturer's Association (PMA) last month accusing Zuma and her officials of making "intellectually dishonest" distinctions between commercial and non-commercial drug prices.

They have argued that these comparisons were aimed at creating a perception that South African drug manufacturers were responsible for unreasonably high costs of medicine.

In a 30-page affidavit the organisation says that Zuma's claims cannot be substantiated, adding there are certain norms for public administration including the provision of "accurate information".

(96) Star 17/7/97

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(96) BD 17/7/97

MEDICINE PRICES (96) FM 18/7/97

Zuma's statistics under scrutiny

The Public Protector is investigating Health Ministry statements on the high cost of medicine after a formal complaint by the Pharmaceutical Manufacturers' Association.

The PMA is asking Public Protector Selby Baqwa to take urgent steps to prevent parliament from considering Zuma's controversial drug reforms until he has completed his investigation.

It alleges the statistics which underpin the Medicine & Related Substances Control Amendment Bill are incorrect. It accuses officials of improper conduct for disseminating inaccurate statistics. These, it says, have created the prejudicial impression that pharmaceutical manufacturers are responsible for what is presented as "the unconscionably high cost of medicine in SA."

The R10bn industry is up in arms over the Bill, which seeks to reduce medicine costs by making the substitution of generic drugs mandatory and allowing anyone to import drugs sourced from countries with a cheaper cost structure than SA (parallel importation).

Baqwa's assistant, Tinus Schutte, says the investigation is being accorded priority as it must be completed before August 11 when parliament reconvenes.

He says the Public Protector could recommend the department issue a formal retraction in parliament if it decides the matter in the PMA's favour.

But he stresses that, "the Public Protector would not want to act as a pressure group on a Bill that parliament has yet to decide on."

The PMA disputes five statements on technical grounds. They are that:

- SA is rated in the top five most expensive countries for medicine;
- Some medicines sell for up to 4 000% above the world average;
- SA pays 2 500% more for anti-tapeworm preparations than the international norm;
- Medicine costs have increased at double the inflation rate over the past 10 years, and;
- Of all the medicine prescribed in SA, generics account for only 16% compared with 48% in the US and 54% in the UK.

On April 14, Zuma rounded on members of the PMA, saying: "3 000%, 4 000%, 5 000% — what difference does it make what prices I quote? We are one of the five most expensive countries in the world."

PMA executive director Mirryena Deeb says the department has told her that Zuma was comparing local private-sector retail prices with the prices of the International Dispensary Association (IDA), a Dutch aid organisation which sells essential drugs to developing countries at reduced prices.

Deeb's affidavit furnishes independent statistics which show the average increase in manufacturing prices between 1987-1997 was 13%-13,7% (in the private sector) compared with a CPI of 11,96% averaged over the same period. Price increases passed on to the public sector were below inflation on average.

The investigation will be the Public Protector's third involving Zuma. The previous inquiries into the *Sarafina 2* affair cleared her of any wrongdoing.

The ministry did not wish to comment.

Claire Bisseker

Zuma and Deeb *. . . disagree on the numbers*

Zuma told to explain claim

CT 19/7/97 (96)

OWN CORRESPONDENT

DURBAN: Health Minister Dr Nkosazana Zuma has been ordered by the Public Protector to substantiate claims allegedly made by the ministry that the cost of medicines in South Africa are among the highest in the world.

This follows a detailed 30-page complaint, made last month by the Pharmaceutical Manufacturers' Association (PMA), to Public Protector Mr Selby Baqwa.

The Minister's spokesman Mr Vincent Hlongwane confirmed that they had received a document on Wednesday from the Public Protector asking them to respond to the complaint.

Hlongwane said it was too soon to comment as they had not yet gone through the entire document.

The statements at issue — allegedly made by the minister and other officials of the Department of Health — include:

- "South Africa (is) rated in the top five most expensive countries in the world for medicine.".
- "Some medicines sell in South Africa for up to 4 000% above the world average.".
- "South Africa pays, for example, 2 500% more for anti-tapeworm preparations ... than the international norm.".
- "Medicine costs ... have increased at double the inflation rate over the past 10 years.".
- "Prescription of generic medicine in South Africa, at 16%, lagged behind countries like the United States at 48%, and Britain, at 54%."

In the document, PMA chief executive Ms Miryena Deeb requests the Public Protector to decide whether the statements were proper conduct on the part of Zuma and other health officials.

In a statement the Public Protector said the PMA had alleged that "inaccurate or offending statements ... are creating the perception ... that medicines in South Africa are unreasonably expensive and that the blame ... lies with the manufacturing companies".

Zuma's health bills worse now — DP

BD 20/8/97 (96)

Jacob Dlamini

CAPE TOWN — The Democratic Party (DP) yesterday accused Health Minister Nkosazana Zuma of trying to impose centralised control of health care after two controversial bills, withdrawn amid fierce opposition in June, were retabled in Parliament yesterday.

DP spokesman Mike Ellis said the bills would give Zuma a great deal of power and authority to draw up legislation on her own and without consultation with various stakeholders.

Ellis said the bills tabled yesterday were worse than the versions withdrawn in June following vociferous opposition from the pharmaceutical industry and other interested parties.

If they became law, the new bills would give Zuma control of statutory health bodies, Ellis said.

He said in terms of the proposed new legislation, Zuma would have the power to approve the composition of the Medicines Controls Council and the right to fire the council's registrar.

The Medicines and Related Substances Control Amendment Bill and the Pharmacy Amendment Bill are designed to improve access to affordable health care by lowering the price of medicines.

The Medicines Bill retains key provisions regarding the fast-track registration of essential drugs, the parallel importing of drugs, and the prohibition of the bonusing and sampling of medicines.

The bill also contains provisions designed to give the health department director-general powers to grant licences for the dispensing of medicines.

The Pharmacy Amendment Billincludes, among others, a measure intended to open the ownership of pharmacies to people other than qualified pharmacists.

Parliament's health committee is scheduled to hold a round of hearings on the bills, during which pharmacy industry stakeholders will be asked to make submissions.

Ellis said he hoped opposition parties would form a united front to oppose the proposed new health-care legislation.

"There is a trend in this bill that gives the health minister more powers than has been the case before," Ellis said.

"We believe that no minister should have the right to draft legislation which affects the lives of other people on her own, and we plan to oppose this legislation."

Friday August 22 1997

Making medicine more affordable

(96)

STAFF REPORTER

Star 22/8/97

The new Medicines Bill tabled in Parliament this week is aimed at making medicine more affordable to the public, says Dr Olive Shisana, the Director-General of Health.

The bill introduces several cost-cutting measures, including substituting generic medicines for more expensive brands and the licensing of dispensing doctors.

In a statement yesterday, Shisana said legislation would promote medicines which contained the same active substances as the innovator medicines prescribed by doctors.

"We believe that the new bill (called The Medicines and Related Substances Control Amendment Bill) will reduce the cost of medicines and at the same time protect the public against harmful products."

The bill also provides for the parallel importation of drugs under strictly controlled circumstances. Imports would have to meet exactly the quality standards as medicines already registered in SA.

Zuma's battle of the Bills

(96) (183) (93)

CYRIL MADLALA
Political correspondent

ST 24/8/97

A SHOWDOWN is looming between the Minister of Health, Dr Nkosazana Zuma, and pharmaceutical manufacturers over three controversial laws she is proposing.

The laws were withdrawn from Parliament in June after severe criticism from the industry, the medical profession and opposition parties.

Zuma has resubmitted the Bills to cabinet, which approved certain changes before they were tabled again in Parliament this week.

The three laws are the Medical, Dental and Supplementary Health Services Professions Amendment Bill, the Medicines and Related Substances Control Amendment Bill, and the Pharmacy Amendment Bill.

The Pharmaceutical Manufacturers' Association and opposition parties say the laws do not protect patents. They are also unhappy that Zuma wants to allow the importation of some medicines should they be cheaper.

Inkatha's spokesman for health, Dr Ruth Rabinowitz, says: "She is waging all-out war on the private sector by over-regulating and ignoring patent rights."

The association, which represents 43 multinationals, says infringing patent rights would drive these companies away.

There are also fears that parallel importation would result in a flood of counterfeit medicines.

The director general of health, Dr Olive Shisana, says: "The government has compromised — now it is the industry's turn."

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Health care sector reeling in 'terrible year'

(96) BD 27/8/97

Ingrid Salgado

THE pharmaceutical and medical sector had a "terrible" year, underperforming the Johannesburg Stock Exchange (JSE) industrial index by nearly 20% since January, analysts said yesterday.

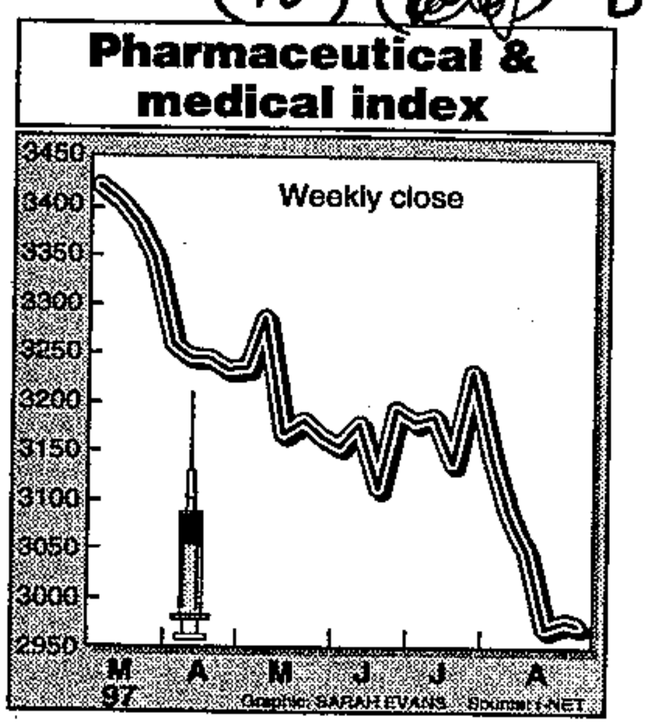
The downward trend was expected to continue, primarily due to uncertainty about the health care legislative environment. "The fundamentals are not in the right direction," UBS Securities analyst Steven Kahanovitz said.

The sector took another knock on the JSE yesterday, losing 4,6 points to close at 2 974,3 points, as most shares lost a portion of their value. Analysts pointed out that many of the losses were made on small volumes.

The biggest losers in percentage terms were pharmaceutical products company Alliance, which lost 20c to close at 190c, medical and surgical equipment supplier Macmed, which shed 25c to end at 425c, and medical, pharmaceutical and consumer products operation Medhold, 2c lower at 41c.

Hospital and surgical equipment supplier Aukland was unchanged at 395c at the close of trade, but took a battering earlier on. Investec Securities analyst Melanie da Costa said there was no fundamental reason why the share price had dropped: "It's probably just following the trend in the sector." Aukland's results, due in two weeks time, would not disappoint the market, she said.

A smaller loser was Netcare, whose share price has fluctuated over the last few weeks after it bought out hospital group Clinic Holdings. Netcare ended the day 3,5% lower at 198c.



Pharmaceutical heavyweight SA Druggists lost 50c to end at R32. An analyst said this anticipated poor financial year results.

Kahanovitz said health care groups were not only going through big changes, but were also in the "painful process" of not knowing what the precise changes were.

Zuma's proposal to allow for the parallel importation of drugs would not affect most firms listed in the sector, he said. Multinational pharmaceutical groups would be hardest hit; listed drug firms SA Druggists and Adcock Ingram could also suffer to some extent.

Kahanovitz said Zuma's "bottom line motivation" to reduce health care costs was "sound". Another analyst said there was no reason why medical equipment suppliers ought to be affected by Zuma's proposals. Yet the atmosphere of uncertainty led the market to "always assume the worst".

Exceptions s yesterday were cosmetics group Carson, whose operations were "unrelated" to sectoral activities, analysts said. The share gained 20c to R19,30. Medi-Clinic, Medex, Adcock and Presmed shares were unchanged.

Public spotlight falls on controversial health bills

CT 2/9/97 (96)

CARNITA ERNEST

THE Portfolio Committee on Health will hold public hearings on three bills this month. They are the Medical, Dental and Supplementary Health Service Professions Amendment Bill, the Pharmacy Amendment Bill, and the Medicines and Related Substances Control Amendment Bill.

The three bills deal with issues relating to the implementation of the National Drug Policy and the reformulation of the Medical and Dental Council and the Pharmacy Council.

The bills were originally tabled in May, but because of concerns raised during the committee hearings the Minister of Health withdrew them from Parliament in June. In particular, concerns about the procedures followed by the Department of Health were raised by all three councils, who stated their displeasure at not being consulted on the final versions which were tabled in Parliament.

The Portfolio Committee, after it heard inputs from the department and the council, requested the department to meet with the Interim Pharmacy Council and the Medicines Control Council, in order to resolve the impasse.

Improvements to the bills relate to technical and legal aspects. This is particularly the situation with the Pharmacy Amendment Bill and the Medicines and Related Substance Control Amendment Bill. As a result of comments made at the public hearings in June, additional changes have also been incorporated. The fundamental principles underlying the bills remain unchanged.

The Medical Dental and Supplementary Health Services Professions Amendment Bill allows for increased representation of persons elected by the Committee of University Principals and the Committee of Technikon Principals. Another new addition is a clause providing for community service. The powers to regulate community service is vested in the minister.

This clause was included as a result of the huge outcry related to vocational training proposed by the Interim National Medical and Dental Council (INMDC). Previous proposals for vocational training are currently being investigated and might be drafted into future regulations.

During the public hearings in June regarding the Pharmacy Amendment Bill there was much debate around the issue of ownership of pharmacies, especially in relation to the legal and practical ramifications. The current bill has improved the wording of the clause relating to ownership, allowing the minister to prescribe who may own a pharmacy.

The Medicines and Related Substances Control Amendment Bill still provides for parallel importation, "generic substitution", and the prohibition of bonusing and sampling. To minimise the possibility of differing interpretations, definitions of technical terms have tightened. Under the new provisions, parallel imported drugs will have to be registered to ensure their safety and quality. This resulted from the concern raised at the public hearings about the possible importation of poor quality drugs as well as possible violation of intellectual property rights. In relation to intellectual property rights, the clause which prohibited the use of "brand names" in state tendering procedures has been removed from the current bill.

As can be expected, when dramatic policy changes are being proposed, this health legislation has been surrounded by controversy. It is particularly troubling that major stakeholders such as the relevant statutory councils and medical interns complained to the portfolio committee that they had not been sufficiently consulted by the department before the earlier amendment bills were introduced. In contrast, concerted efforts have been made to increase public involvement in the legislative process by the Portfolio Committee on Health.

Unfortunately the National Department of Health has not achieved sufficient consensus before submitting its proposals to Parliament. It is hoped that this experience would point to the critical need for thorough consultation before legislation is processed.

The question still remains, however, whether the Department will secure greater ownership of its policies and legislation before they are finalised. The issue of community service also sticks out.

❑ *Carnita Ernest is a research intern with the National Progressive Primary Health Care Network (NPPHCN).*

More power: *Minister could have total control of health care, says DP's Mike Ellis*

Not about numbers: *Ramotena Mabote calls for more commitment to change*

An unhealthy state of affairs

Star 5/9/97 (96)

Zuma's troika of bills affects everyone, yet she need not take any views into account, writes Mike Ellis

One of the most obvious things which distinguishes a democracy from a dictatorship is that in democracies decision-making involves a balance of power between the government and other interest groups. In dictatorships there are no curbs on the state's authority.

Gradually South Africa's Government is amending the rules of the game so it fits more and more into the category of governments accountable to no one. This is particularly obvious in Health Minister Dr Nkosazana Zuma's efforts to control health care.

Zuma's troika of health bills allows her to decide on some crucial aspects of health care without considering the views of any other body and without being subject to requirements of reasonableness or fairness. The bills give her the power to make decisions which in all likelihood will not survive Parliament's scrutiny.

Although the legislation will affect the health care of everyone, the minister need not take the views of anyone into account in making her decisions. One has to ask how much her relationship with Cuba, and her apparent ideological attachment to Cuba's authoritarian government, has to do with her stance.

The Medical, Dental and Allied Health Services Bill will allow Zuma to implement her controversial community service for doctors plan. The only restraint which Zuma faces in deciding on the length of this service, where it should be performed and conditions of work is that she should consult the Interim Medical and Dental Council. This is a formality, because she is under no obligation to accept their advice.

The Health Professions Council is tasked with deciding if a doctor qualified outside South Africa will be permitted to register in SA. But its discretion is "subject to any regulation which the minister may make" – so effectively it has no discretion at all.

If these powers were not already extravagant enough, the bill goes on to say "the minister may after he or she deems it in the public interest, amend or repeal any regulation or rule made in terms of the act". This probably allows her to overrule the already minimal requirement to consult the council. Effectively, the minister will be able to chop and change the legislation at will and without reference to Parliament or any other representative body.

The pattern is repeated in the Medicines and Related Substances Control Amendment Bill, which states a new council can be formed "subject to the approval of the minister". At a bare minimum modern administrative law requires public officials to contain their decisions within the bounds of reasonableness and certainty. Yet this bill places no obligation on the minister to ensure her decisions are reasonable, nor must she provide justifications.

The minister is also given the power to appoint, and to revoke the appointment of, a registrar of medicines. The only constraint is the purely decorative obligation to consult the council. She also appoints the members of an appeal committee, created to give anyone aggrieved by a Medicines Control Council decision a means of addressing their complaint. Her only limitation is that the qualifications of the members of the appeal board are prescribed.

The bill goes on to give the minister the power to "prescribe conditions for the supply of more affordable medicines in certain circumstances". This power is to be invoked unilaterally and without even the figleaf of consultation. Control over medicines is so important that it would not be exaggerating to say, if you lose control over medicines, you lose control over health care. This bill ensures no interested party other than the minister will have any say on how or what medicines will be supplied.

Whatever good or evil may result from the exercise of her discretion, the power to exercise this discretion is unfettered and wide open to abuse, if not by her, then by any successors. As with the previous bill, the minister may decide to amend any or all of these regulations if she wishes and she need only "consult" with the executive committee.

This bill is likely to have immediate consequences. The provision which allows the minister to ignore patent rights for drugs registered in SA probably contravenes SA's intellectual property laws; she has already been threatened with lawsuits by pharmaceutical companies if the bill goes ahead.

The minister is given yet another cluster of powers in the Pharmacy Bill, which allows her to prescribe who may own a pharmacy, under what conditions they may do so and under what conditions permission may be revoked. For an issue as complex and contentious as this, it is astounding the minister should regard it as acceptable that she alone, without consulting even the Pharmacy Council, may make such decisions. Although the Pharmacy Council is rendered almost meaningless by this provision, she has still found it necessary to give herself the power to terminate the membership of any member of the council.

The minister is given extensive powers, among which is the power to increase powers she already has. The consequences in terms of democratic and transparent government are disastrous.

The story does not end with these bills. The real challenge to our private health care service as we know it will come when the National Health Bill, at present in its 9th draft, is tabled in Parliament either at the end of the year or early in 1998. Medical schemes, private practices, private hospitals and all other dimensions of private health care will be challenged by Zuma.

If Zuma grants herself the same powers in this bill as she is attempting to do with the three before Parliament, she will effectively be in complete and sole control of health care. The DP will do its utmost to ensure this does not happen.

■ *Mike Ellis is a Democratic Party MP.*

Doctors rattle sabres over dispensing bills

Pearl Sebolao

BD 5/9/97

THE medical doctors' National Convention on Dispensing has threatened to disrupt health services if the health department goes ahead with three bills which prohibit them from dispensing medicines.

The proposed legislation in contention is the Pharmacy Amendment Bill, Health Professions Amendment Bill and the Medicines and Related Substances Amendment Bill.

Medical doctors and other stakeholders would, however, make their submissions to parliamentary health committee hearings which were scheduled to start next Thursday, but if the health department ignored their input they would have to act, convention chairman Norman Mabasa said on Wednesday.

Mabasa said the convention adopted a resolution at a meeting on Saturday to embark on a series of actions including protest marches, the closure of private practices for a number of days and a refusal to render services at public health institutions.

A mass media campaign would also be planned to inform the public about the implications of the bills and to rally the support of the community, he said.

The convention — representing the Medical Association of SA, Medical and Dental Practitioners' Association, Family Practitioners Association and other associations — was consulting trade unions, the SA National Civic Organisation and the Black Consumer Organisations, who had endorsed the resolutions, Mabasa said.

The profession was determined to fight against those provisions which they felt discriminated against them, especially the repeal of section 52 in the Health Professions Amendment Bill which permitted doctors to dispense.

"We are greatly disturbed by the proposed Pharmacy Amendment Bill which would allow almost anybody to own pharmacies with the exception of doctors and dentists. We feel we are as able and competent as anybody else," Mabasa said.

Parallel importing of drugs aims to lower prices — Zuma

Jacob Dlamini BD 10/9/97

CAPE TOWN — Government would not introduce the parallel importing of drugs if pharmaceutical companies agreed to sell the state patented drugs at competitive prices, Health Minister Nkosazana Zuma said yesterday.

Plans to introduce parallel importing had been prompted by government's aim to lower the price of medicines by encouraging the use of generic medicines.

She denied that her plans would violate World Trade Organisation regulations, saying the parallel importing clause had been examined and pronounced satisfactory by the trade and industry department.

Zuma rejected suggestions that her relations with the pharmaceutical industry had deteriorated. She said only those companies dealing with patented drugs were unhappy with her plans while those responsible for producing generic drugs had welcomed them.

Zuma also dismissed suggestions that the government wanted to impose community service on newly qualified doctors. She said medical students had asked for community service to be included in health reforms currently before Parliament. (96)

Zuma said the introduction of vocational training was a responsibility of the interim national medical and dental council. While the council had temporarily shelved its plans to introduce the system next year, it remained its domain and she would be guided by it on the matter, she said.

Josey Ballenger reports the National Interns Alliance has objected to Zuma's bill on compulsory community service due for discussion by Parliament's health portfolio committee tomorrow and Friday.

The alliance, which said interns supported "the concept" of community service and restructuring the health service, objected to the lack of infrastructure at medical facilities, the "authoritarian powers" it claimed the bill would give the minister and the "late notification" of compulsory service from January.

"The lack of infrastructure in the facilities where compulsory community service is meant to take place will result not only in the failure of delivery of health services to the community, but also destroy the medical delivery in the major centres such as Soweto and Atteridgeville," the alliance said.

Press officer Dr Yair Safriel said: "The minister has created the perception that if you put a doctor in a room, you will solve health problems. But that is naive. Medicine today is very infrastructure-based, even with something basic like laboratory tests and chest x-rays."

Safriel said the bill gave the minister powers to bypass the Medical and Dental Council and Parliament, which "sets a very dangerous precedent in a democracy". The alliance contended the bill will allow the minister to send practitioners "army-style to an area she chooses, irrespective of their wishes" and to lengthen their service indefinitely.

Medical schemes and pharmacists agree at last

BD 11/9/97

Pat Sidley

(96)

MEDICAL schemes and the retail pharmacy industry have finally reached agreement on a new scale of benefits to reimburse the costs of medicines to medical scheme members.

The new scale of benefits, effective from January 1 next year, will affect about 7-million people who belong to medical schemes.

Agreement between medical schemes and the retail pharmacy industry have been dogged by disputes.

RAMS announced yesterday that medical schemes would reimburse for pharmaceutical products according to a sliding scale using three tiers to its new reimbursement system.

It will require considerable arithmetical ability on the part of members of medical schemes, and is aimed at providing incentives for the supply of cheaper generic substitutes in place of the more expensive brand name medicines.

Cheaper drugs, which cost pharmacists up to R30 a prescription item, will be reimbursed by medical schemes at that price plus a 50% mark-up.

Drugs costing between R30 and R80 will be charged at the cost price to the pharmacist plus a dispensing fee of between R15 and R24, calculated on a sliding scale.

Drugs which cost more than R80 a prescription will be charged at their cost price plus a dispensing fee of R24.

Announcing the agreement yesterday, RAMS policy director Dr Aslam Dasoo said RAMS had found it impossible to prise loose from pharmaceutical manufacturers the prices at which drugs left their factories. The association had been forced to deal with the retail end of the industry only and would publish a list of its cost prices next week.

Dr Zuma's revolution gets under way

ARG 11/9/97

JOVIAL RANTAO
ARGUS CORRESPONDENT

Nkosazana Zuma has started a revolution.

The Health Minister intends to revolutionise the health system in South Africa to bring affordable, quality health to all South Africans irrespective of their economic status.

The Portfolio Committee on Health, chaired by African National Congress MP Abe Nkomo, will hold public hearings on the minister's three bills during the next 10 days, starting this afternoon.

Once approved, the three pieces of legislation will enable the Government to redress past imbalances, where the majority of South Africans had little or no access to basic health care.

Revolutions always elicit a strong response and Dr Zuma's was no different. Soon after she gave notice that she would table the legislation, a torrent of opposition followed, mostly from political parties rival to the ANC, pharmaceutical companies and some medical practitioners.

Concerns that insufficient time was allocated for public hearings on the bills led to their withdrawal from Parliament. The bills were amended to accommodate major concerns from stakeholders and have been approved by Cabinet and re-tabled in the National Assembly.

The three pieces that Dr Zuma has tabled are:

- The Medicines and Related Substances Control Amendment Bill.
- The Pharmacy Amendment Bill.
- The Medicine, Dental and Supplementary Health Service Profession Amendment Bill.

The objective of the Medical and Related Substances Control Amendment Bill is, among others, to enable Dr Zuma to parallel import drugs from other countries. Through parallel importation a product can be imported from a country where the same product, made by the same company, is available at a much lower price.

The legislation would also force dispensing doctors to be licenced and discourage them and pharmacists from dispensing for a profit.

The Pharmacy Amendment Bill provides for the ownership of pharmacies by non-pharmacists. The Department of Health has argued that many communities in rural areas and black townships do not have access to full pharmaceutical services. This is partly because individual pharmacists have found it not to be financially viable to set up practice in these areas.

The legislation seeks to make it possible for those people who have the ability to set up pharmacies in the underserved areas – but who are not pharmacists – to do so. The only condition is that the pharmacy must be operated under full supervision and management of a qualified and registered pharmacist. The Medicine, Dental and Supplementary Health Service Profession Amendment Bill provides for compulsory community service for newly-qualified doctors, as a way of getting doctors to work in under-served areas.

According to the legislation, junior doctors would be required to do community service before being registered to practice.

Health Director-General Dr Olive Sishana said the measure was also a way to stop foreign countries from poaching newly qualified doctors and denying them a chance to contribute something to the SA taxpayer.

Dr Zuma has held discussions with medical interns, junior doctors, trade unions and other stakeholders about community service.

Health bills give Zuma unfettered powers

(96) CT 11/9/97

THE TROIKA of health bills introduced to Parliament by Health Minister Dr Nkosazana Zuma will have dire consequences for democratic and transparent government, argues **MIKE ELLIS.**

ONE of the most obvious things which distinguishes a democracy from a dictatorship is that in democracies decision-making involves a balance of power between the government and other interest groups, while in dictatorships there are no curbs on the state's authority.

Gradually South Africa's new government is amending the rules of the game so that it fits more and more into the category of governments which are accountable to no one.

This is particularly obvious in Health Minister Dr Nkosazana Zuma's efforts to control healthcare.

Zuma's troika of new health bills allows her to decide on some crucial aspects of healthcare without considering the views of any other body and without being subject to requirements of reasonableness or fairness.

The bills will give her the power to make decisions which in all likelihood would never survive Parliament's scrutiny. Despite the fact that the new legislation will affect the healthcare needs of everyone in the country, the minister need not take the views of anyone into account in making her decisions.

Indeed, one has to ask how much Zuma's close relationship with Cuba and her apparent strong ideological attachment to that country's authoritarian government has to do with her stance on these bills.

The Medical, Dental and Allied Health Services Bill will allow Zuma to implement her controversial community service for doctors proposal. The only restraint which Zuma faces in deciding on the length of this service, where it should be performed and conditions of work is that she should consult with the Interim Medical and Dental Council. This is a formality, because she is under no obligation to accept their advice.

DR NKOSAZANA ZUMA: Bills to be introduced in Parliament could put her in complete and sole control of health care in this country if they are passed as they are now written.

With regard to foreign doctors, the Health Professions Council is tasked with deciding whether a doctor qualified outside the Republic will be permitted to register in South Africa. But its discretion is "subject to any regulation which the minister may make". Effectively, therefore, it has no discretion at all.

As if these powers were not already extravagant enough, the bill goes on to say: "The minister may after he or she deems it to be in the public interest, amend or repeal any regulation or rule made in terms of the Act."

This probably allows her to overrule the already minimal requirement to consult the council. Effectively, the minister will be able to chop and change the legislation at will and without reference to Parliament or any other representative body.

The pattern is repeated in the Medicines and Related Substances Control Amendment Bill. It states that a new council can be formed "subject to the approval of the minister".

At a bare minimum, modern administrative law requires public officials to contain their decisions within the bounds of reasonableness and certainty. Yet this bill places no obligation on the minister to ensure that her decisions are reasonable, nor must she provide justifications.

The minister is also given the power to appoint, and to revoke the appointment of, a Registrar of Medicines. The only constraint on her power is the purely decorative obligation to consult the council. She also appoints the members of an appeal committee — created to give anyone aggrieved by a decision of the Medicines Control Council a means of addressing their complaint. Her only limitation is that the qualifications of the members of the appeal board are prescribed.

The bill goes on to give the minister the power to "prescribe conditions for the supply of more affordable medicines in certain circumstances". This power is to be invoked unilaterally and without even the fig-leaf of consultation. Control over medicines is so important that it would not be exaggerating to say that if you lose control over medicines, you lose control over healthcare.

This new bill will ensure that no interested party other than the minister herself will have any say on how or what medicines will be supplied in the future.

Whatever good or evil may result from the exercise of her discretion, the power to exercise this discretion is unfettered and wide open to abuse — if not by her, then by any of her successors.

As with the previous bill, the minister may decide to amend any or all of these regulations if she wishes and she need only "consult" with the executive committee in order to do so.

This bill is likely to have immediate consequences. The provision which allows the minister to ignore patent rights for drugs registered in South Africa probably contravenes South Africa's intellectual property laws; she has already been threatened with lawsuits from pharmaceutical companies if the bill goes ahead.

The minister is given yet another cluster of powers in the Pharmacy Bill, which allows her to prescribe who may own a pharmacy, under what conditions they may do so and under what conditions permission may be revoked.

For an issue as complex and contentious as this, it is astounding that the minister should regard it as acceptable that she alone, without consulting even the Pharmacy Council, may make such decisions.

Furthermore, although the Pharmacy Council is rendered almost meaningless as a result of this provision, she has still found it necessary to give herself the power to terminate the membership of any member of the council.

In summary, the minister is given extensive powers, among which is the power to increase the powers which she already has. The consequences in terms of democratic and transparent government are disastrous.

The story does not end with these bills. The real challenge to our private healthcare service as we know it will come when the National Health Bill, at present in its ninth draft, is tabled in Parliament either at the end of the year or early in 1998.

Medical schemes, private practices, private hospitals and all other dimensions of private health care will be challenged by Zuma. If she grants herself the same powers to regulate in this bill as she is attempting to do with the three before Parliament now, she will effectively be in complete and sole control of healthcare in South Africa.

The DP will do its utmost to ensure that this does not happen.

❑ *Mike Ellis is the Democratic Party's spokesperson on health. He was last year voted the best opposition MP in Parliament by Sunday newspapers.*

Pharmaceutical firms, med-aids near accord

Star 12/9/97

Three-tiered compromise on original idea for drugs pricing system seems to have found favour with main role players

96

JANINE SIMON
Medical Correspondent

Medical aids and the pharmaceutical industry finally appear to be nearing agreement on a new drug pricing system.

Representative Association of Medical Schemes (RAMS) said this week the new system would be introduced on January 1 1998.

It is a three-tiered compromise on the initial idea that the profit mark-up on all drugs be replaced with a professional dispensing fee.

The only dissenting voices come from a a group which queried one section of the compromise, and the United South African Pharmacies (USAP), whose chairman Julian Solomon said his 1 600 members had not yet seen the proposal, but that it appeared novel and worth consideration.

RAMS said the new pricing structure was based on a new medical aid tariff list for drugs called the RAMS Recommended Pharmaceutical Scale of Benefits.

This is a groundbreaking set of guidelines on how a medical aid should reimburse a pharmacist or other supplier for drug costs.

According to the benefit scale, drugs which cost a retailer more than R80 will be sold with a R24 dispensing fee and drugs which cost the retailer between R30 and R80 will be sold with a dispensing fee calculated on an evenly-adjusted sliding scale.

Current proposal politically acceptable

Drugs which cost a retailer less than R30 will be sold with a 50% mark-up.

This proposal meant expensive drugs will become cheaper and cheaper drugs will not become more expensive, the RAMS said.

Earlier this year medical aids strongly attacked the pricing changes, saying the across-the-board introduction of a dispensing fee would dramatically increase the price of cheaper drugs and costs of medical aids with low-income members who relied on generic drugs.

The RAMS said its current proposal was politically acceptable to all parties, economically equitable and set the correct prescribing and dispensing incentives.

However, some groups had expressed reservations about the proposed mark-up system for cheaper items. They had until year-end to present an alternative proposal, providing it did not increase the overall price for drugs wholesaling under R30.

Drug companies still on major collision course with minister

BY JANINE SIMON

Increasingly jittery pharmaceutical manufacturers and Health Minister Nkosazana Zuma remain on a collision course over the controversial new medicines legislation.

The R10-billion industry says fundamental threats to its patent and intellectual property rights are still in the revised bill, threatening both its survival in the country, and consumer safety.

Mirryena Deeb, executive director of the Pharmaceutical Manufacturers Association (PMA) said the PMA would have no choice but to challenge the Act 101 Medicines and Related Substances Control Amendment Bill in court.

However, health director-general Dr Olive Shisana said last week the department believed it was not contravening any existing international agreements.

"We believe we are on solid legal grounds on this issue," she said. "We believe we are acting within the letter and spirit of existing international agreements and we have explained our position time and time again in discussions with the pharmaceutical industry about parallel importation."

Deeb claimed this week that Zuma appeared to be motivated by a movement gaining ground in the World Health Organisation, which advocated there be no patent protection for pharmaceuticals worldwide.

The movement was based on a paper presented by a pirate pharmaceutical manufacturer in South America with a direct pecuniary interest in the matter, Deeb claimed.

The bill was withdrawn in June and resubmitted in August, following widespread opposition, including from the industry, the Medicines Control Council and opposition parties.

But principles in the revised bill remain unaltered, and in some instances, are worse than the bill which was withdrawn, Deeb says.

The industry was stunned that the minister was seeking in clause 15 C (a) of the new bill the power to abrogate all patent rights under the Patent Act at her discretion. This was despite the fact that she had met with the American pharmaceutical industry and heard its grave reservations on how parallel imports would infringe intellectual property rights (TRIPS).

The PMA was concerned that the Cabinet was not aware of the scope of the proposals, as it could not possibly be ready to contemplate violating TRIPS.

The bill proposed unequal registration and control standards as the minister would have the final say in the event of any dispute with the Medicines Control Council.

It also gave the minister wide and undefined powers through unlimited authority to make regulations , Deeb said.

Public hearings on the bill are scheduled for next week.

Hawkers selling stolen medicine

9b

Star 13/9/97

By ADELE BALETA and JILYAN PITMAN

Cape Town – Dangerous stolen medicines, including prescription drugs, have found their way on to the streets in several major cities, where they are being sold by hawkers with no medical knowledge.

The medicines have been stolen mostly from state depots and are being sold at cut-rate prices.

Health professionals have warned the public it is hazardous to buy medicines from street vendors.

They said the drugs' shelf life could have expired, although the packaging may indicate otherwise. The contents could be counterfeit or poor-quality generics. The drugs could be harmful if taken without professional medical advice.

A pharmacist said medicines had to be kept in optimal conditions and it was dangerous, for example, "to leave them in the blazing sun".

Some of the medicines sold on the streets include steroid creams meant to treat skin conditions, which are being sold as skin lighteners and which could damage skin irreparably. Hawkers are even selling asthma inhalers, which must be bought at pharmacies.

Medical experts warn that deaths due to asthma are usually the results of patients underestimating the severity of their disease and relying on these inhalers when they in fact needed more treatment.

An intricate web of illegal trading in medicines, involving organised-crime syndicates and individuals, is costing the Government millions of rands and putting people's health at risk.

Investigators into theft of medicines said scheduled drugs – those for which a doctor's prescription was needed – were stolen and sold by individuals to middlemen who in turn sold them to unscrupulous wholesalers.

Stolen drugs have made their way on to the streets of all major cities, including Cape Town.

In Kalk Bay, 12 Ventolin refills – a popular asthma inhalant – have been confiscated from a hawker trading from outside the Mitchell's Plain Town Centre.

Mogamet Shafiek of Beacon Valley, Cape Town, has appeared in court for allegedly selling the stolen refills and his case was postponed for further investigation. Sergeant Craig Finlay said Shafiek allegedly bought the refills for R7 each and sold them for R20.

WATCH OUT FOR THESE MEDICINES

ARG 13/9/97 (96)

ADELE BALETA AND JILYAN PITMAN

Potentially dangerous stolen medicines, including prescription drugs, are being sold on the streets of Cape Town and other cities by hawkers with no medical knowledge.

City police have confiscated some medicines on the streets of Cape Town, and at least one case is being heard in court.

The medicines, most of which have been stolen from state depots, are being sold from street corners and shopping centres countrywide for cut-rate prices. Health professionals have warned the public it is hazardous to buy medicines from street vendors.

They said the drugs' shelf life may have expired even if their packaging indicated otherwise, because the contents could be counterfeit. They could also be poor-quality generics.

The drugs could be harmful if taken without professional advice.

A pharmacist said medicines had to be kept in optimal conditions. It was dangerous, for example, "to leave them in the blazing sun".

Some of the medicines include steroid creams, such as Betnovate,

Health hazard: asthma pumps sold on streets

meant to treat skin conditions, being sold as skin lighteners. These could damage the skin irreparably.

Hawkers are even selling asthma inhalers, which have to be bought at pharmacies. Medical experts warned that deaths due to asthma usually took place as a result of patients underestimating the severity of their condition, relying on inhalers when they needed more serious treatment.

An intricate web of illegal trading in medicines involving organised crime syndicates is costing the Government millions of rands.

Bada Pharasi, the Health Department's chief director of medicines, registration, regulation and procurement, estimates that the cost of theft ranges between R50-million and a billion a year, but sources in the pharmaceutical industry said these figures were "too conservative".

Investigators into theft of medicines said scheduled drugs – those which require a doctor's prescription – were stolen and sold by individuals to middle-men, who in turn flogged them to "unscrupulous" wholesalers.

Kalk Bay police have confiscated 12 Ventolin refills – a popular asthma inhalant – from a hawker trading outside the Mitchell's Plain Town Centre. Mogamet Shafiek of Beacon Valley has appeared in court for allegedly selling the stolen refills. His case was postponed to September 29.

Kalk Bay sergeant Craig Finlay said Mr Shafiek allegedly bought the refills for R7 each and sold them for R20 each. City pharmacists told Saturday Argus that their retail price varied from R39,99 to R55,20.

Anne Brand, Western Cape Health Department Director of Health Support Services, confirmed that the stock had been stolen from the province's Medical Depot in Chiappini Street. She said a total of 86 refills

To page 3

P.T.O.

New pharmacies bill under fire

ARG 15/9/97 (96)

JENNY VIALL
HEALTH REPORTER

Opening pharmacy ownership to non-pharmacists will have "serious repercussions", says Julian Solomon, of United South African Pharmacists, who represent independent community pharmacies.

He told the parliamentary portfolio committee on health yesterday that no mention was made in the Pharmacy Amendment Bill of the criteria to be used to select those who could own pharmacies.

The bill would make it possible for large retail chains to own pharmacies as it allowed anyone except a doctor to own a pharmacy. It said a licence would be granted "under certain conditions" but the conditions had not been spelled out.

Mr Solomon said chain store ownership would result in smaller pharmacies closing with a loss of service mainly in under-serviced areas.

Ian Roberts, special adviser to Health Minister Nkosazana Zuma, said there was nothing in the bills, which were bringing laws in line with the national drug policy, that was anti-competition. "Large chains in the UK have not put small businesses out of work."

Body opposes dispensing fee

(96)

Jacob Dlamini

CAPE TOWN — The Interim Pharmacy Council of SA would not support the introduction of a fixed dispensing fee as proposed in Medicines and Related Substances Amendment Bill, council registrar Jan du Toit said yesterday.

Du Toit said a fixed dispensing fee would not be in the public interest and may keep the price of drugs high.

The bill is one of three pieces of legislation designed to improve access to health care by lowering the price of drugs, encouraging the use of generic drugs and parallel importing medicines from cheaper sources. But Du Toit said he welcomed provisions in the bill which would give the council powers to determine the procedure to be followed by pharmacists when they charged dispensing fees.

Du Toit said the council also supported mechanisms that would guarantee the safety, quality and efficiency of medicines offered by pharmacists.

BD 16/9/97

Eskom guarantees medical aid payments

Robyn Chalmers

BD 16/9/97

ESKOM has issued a letter to suppliers and service providers to the ailing Esmed medical aid scheme guaranteeing payment for all valid claims submitted by Esmed members.

A copy of the letter, issued by the Mineworkers' Union to its members, said administrative and financial difficulties being experienced by the scheme were of "extreme concern". Eskom executive director Jac Messerschmidt said it was Eskom's intention to ensure that services by suppliers to Eskom employees should continue on credit as before, without suppliers demanding cash for services rendered.

"To the above end, Eskom guarantees payment to suppliers for all valid claims in respect of services rendered to all beneficiaries of Esmed under the scheme," he said.

Mineworkers' Union general secretary Flip Buys said the union had alerted its members to the possibility that Esmed was heading for bankruptcy, and action was needed urgently.

Buys said a union bulletin had "shaken" Eskom and Esmed to the extent that Eskom CE Allen Morgan had offered to put an executive director on Esmed to sort out its problems. Messerschmidt had subsequently taken over management of the scheme. The scheme, which caters for about 40 000 employees, would continue as normal.

Messerschmidt said at the weekend the medical aid fund's surplus had dropped dramatically since the beginning of the year and cash flow projections were not rosy. "It's losing several million rands a month," he said.

Esmed began operating in January after the demise of the Eskom Medical Aid Society. More than 75% of 40 000 employees had opted for or defaulted to Esmed's managed care option.

Blue Waters HOTEL
BUSINESS CLASS
BEST VALUE

Zuma's plan to open up ownership of pharmacies supported

Star 16/9/97 (96)

By Jovial Rantao
Political Correspondent

Cape Town – Health Minister Dr Nkosazana Zuma's plans to open up the ownership of pharmacies to ordinary citizens to improve the accessibility for all disadvantaged communities has received cautious support from most stakeholders.

There were no major objections yesterday as the Interim Pharmacy Council (IPC) and other organisations in the pharmaceutical industry made their presentation to Parliament's Health Committee.

Most presenters appealed for the bill's language to be simplified.

The IPC said the majority of its problems had been addressed.

The council, however, raised objections of a technical nature.

It said these objections could create problems with interpretation and the day to day implementation of the Pharmacy Amendment Bill, once it became law.

Pierre Marais, an IPC representative, said the council had a problem with the involvement of Zuma in its disciplinary processes.

The Pharmacy Amendment Bill also gives the IPC authority to determine the procedures for which a pharmacists may charge a professional fee.

IPC registrar Jan du Toit said the council was against a fixed dispensing fee as proposed by Zuma in a separate legislation.

"Council supports any mechanism – provided appropriate safeguards are in place to ensure safety, quality and efficiency of medicine in the public interest – that could bring down the price of the medicine in SA," Du Toit said.

Julian Solomon of the United South African Pharmacies said that by not mentioning the criteria under which a licence to operate a pharmacy may be issued, the department was asking stakeholders to "give a blank cheque to the authorities".

"It will be a suicidal commitment, if we don't have the criteria clearly spelt out. The proposal to allow any non-qualified person or companies to own a pharmacy, can be disastrous, if not controlled correctly," Solomon said.

■ **Sapa** reports from Durban that Zuma yesterday repeated her determination to deploy more doctors in rural areas, but denied they would be "conscripted" after their training.

Zuma said she saw the training and recruitment of doctors for rural areas as a priority.

However, she denied this amounted to "conscription". Zuma's plan requiring doctors to serve in rural areas for a period after completing their studies caused an outcry earlier this year.

She appealed to academic institutions to assist the process by recruiting people from rural areas for training as medical staff.

"I appeal to universities to send students to rural areas so they can learn from doctors there and adopt them as role models," she said.

Chamber of Mines welcomes pharmacies licensing changes

(96) BD 17/9/97

Jacob Dlamini

CAPE TOWN — The Chamber of Mines yesterday welcomed Pharmacy Amendment Bill provisions giving the health department director-general powers to issue licences to run pharmacies.

Chamber spokesman Lettie La Grange said director-general Olive Shisana was an independent party who could grant licences without regard to vested interests.

Licences for the running of pharmacies are currently issued by the Interim Pharmacy Council. But La Grange said the Chamber of Mines had suffered because of a council decision to withdraw its licence to operate pharmacies at its 43 hospitals and 300 clinics last year.

The decision was taken to protect council members who had complained the chamber was taking away their business by offering pharmaceutical services to its estimated 500 000-strong workforce.

La Grange said the council should not get involved in the "economics" of pharmacy ownership, but she strongly backed the amendment bill provision for lay ownership of pharmacies as it would make health care more efficient, cost-effective and accessible.

La Grange also called for the criteria used to decide the awarding of licences to be made transparent and open.

Meanwhile, the Township Pharmacy Group said provisions giving the director-general discretionary powers to issue licences were misplaced. Spokesman Shaheen Sattar said the Interim Pharmacy Council was the only logical body to issue licences.

Sattar called for pharmacists in townships to be given opportunities to grow, and called on the health minister not to grant chain stores licences to operate in townships, as this would lead to the elimination of small community pharmacists. Lay ownership should only be allowed in areas with no pharmaceutical services.

□ Sapa reports Deputy Minister Essop Pahad apologised in the National Assembly for implying in a speech, made more than a year ago, that Democratic Party health spokesman Mike Ellis was in league with hidden pharmaceutical interests.

Natural remedies face ill wind in control Bill

JENNY VIALL (96)
HEALTH REPORTER

ARG 17/9/97

The sale of natural health products like vitamins and herbal remedies is threatened by the Medicines and Related Substances Control Amendment Bill.

Complementary and traditional healing groups will today ask the parliamentary portfolio committee on health to exempt natural substances from the definition of medicine.

They will also ask for their own regulatory body, as they say the Medicines Control Council is not qualified to regulate natural medicines.

They say the Bill needs to be changed to accommodate various cultures of healing, because as it stands it serves only the western medical model.

The definition of a medicine was so broad that substances like garlic and parsley fell under the same control as patent medicines.

The 1965 legislation was put in place to protect consumers against potential disasters like thalidomide.

There is no legislation governing natural products, which have fallen under the jurisdiction of the Act. So health shops selling vitamins and other remedies are technically selling drugs, and are liable for prosecution.

Objections to Zuma's bill

Mixed response to proposals on pharmacy ownership

(96)

Star 17/9/97

By Jovial Rantao
Cape Town

Township pharmacists have strongly objected to Dr Nkosazana Zuma's plans to open the ownership of pharmacies to non-pharmacists as they fear being eliminated out of the market by "medical mercenaries".

Shaheen Sattar, a representative of the Township Pharmacy Group (TPG) stressed that lay ownership of pharmacies must only be permitted in areas where there were no pharmaceutical services.

"We implore the minister, not to grant licences to the giant business moguls, and other medical mercenaries, some of them foreign, to open pharmacies in townships, where they would eliminate the small independent pharmacies, which did their best to serve the oppressed during the previous phase of the struggle.

"It's our turn and our right to be given opportunities to upgrade our practices so that we can provide a far better pharmaceutical service to our communities," he said.

He said in the townships, pharmacists also faced exploitation from the medical profession.

The TPG has also proposed that some parts of the Pharmacy Amendment Bill be reworded because while the draft legislation would prevent collusion and the improper relationship between the prescriber and the pharmacists, it could also obstruct and prevent the development of true group practices where both professions would become equal partners in the interest of the patient.

The organisation requested a further amendment to force Zuma to consult the Pharmacy Council before approving a licence to own a pharmacy.

The TPG objected to the director-general being given the power to grant or refuse licences for the premises from which a pharmacy would be conducted. They wanted those powers to be given to the Pharmacy Council.

The draft legislation was supported by the Chamber of Mines.

Lettie La Grange, medical adviser to the Chamber of Mines said the organisation was in favour of the director-general getting power to grant licences to pharmacies.

"We would like the director-general to have the powers because unlike the Pharmacy Council, the civil servant will be independent. We support that ownership of pharmacies should be opened up but pharmacies should be operated by qualified pharmacists," La Grange said.

The Chamber of Mines was unhappy with the proposed system to govern ownership of the pharmacies, which it described as "cumbersome bureaucratic".

Legislation on drugs may lead to double standards — critics

Jacob Dlamini

CAPE TOWN — The Medicines Control Council yesterday accused Health Minister Nkosazana Zuma of reneging on agreements and seeking to introduce legislation which would lead to double standards in the control and monitoring of efficacy of drugs.

Speaking during a parliamentary hearing on the Medicines and Related Substances Control Amendment Bill, chairman Peter Folb said recommendations by the council had not been included in the bill.

Instead the health department had included clauses in the bill which would affect the council's scientific decision making relating to the safety, quality and efficacy of drugs, Folb said.

He said the draft legislation would give the health minister sweeping powers to introduce the parallel importation of drugs and international tendering, despite assurances by Zuma that she had no intention of usurping the council's powers.

Folb said the bill — one of three pieces of legislation withdrawn by Zuma in June amid intense opposition — also retained clauses which could severely harm the medicines control process and allow for double standards to be used to register and control medicines.

The bill, if passed unchanged by Parliament, would enable the health minister to override or ignore the council's advice, Folb said. Zuma, he said, had been given poor advice on the draft legislation and this had resulted in the bill being "ridiculous" and "thoroughly" unsound. He also said the bill would expose the council to possible legal action by making it a juristic person.

Health department director-general Olive Shisana rejected accusations that the bill would give the minister wide and unspecified powers. Shisana said it was in the public interest for the government to regulate private health care.

She said government would be failing in its duties if it did not intervene appropriately in the market to ensure that the price of medicines was lowered.

Meanwhile, the SA Chamber of Business has called for the withdrawal of the bill, saying it could have damaging economic and legal consequences.

BD 18/9/97

Minister poorly advised on medicines bill, says professor

(96) ARG 18/9/97

JENNY VIALL
HEALTH REPORTER

Proposed legislation to bring down medicine prices is "essentially flawed" and will undermine the drug policy it intends to support, says Medicines Control Council chairman Peter Folb.

In his submission to the parliamentary health committee, Professor Folb said aspects of the Medicines and Related Substances Control Amendment Bill were "thoroughly unsound".

Positions agreed to by the council and the Department of Health had been reneged on by the department.

He said there were two fundamental issues which could not allow the bill to go ahead.

One was parallel imports which would allow medicines to be imported from another country from the same company without registration.

"It is not sufficient to depend on the name of the manufacturer: a reputable company in one country could be disreputable in another.

"Medicines from whichever source should be treated in the same way," said Professor Folb.

There could be no endorsement of double standards in the regulation and control of medicines (one standard for the State and one for everyone else).

"I feel the minister has had poor advice and the result in parts is ridiculous."

The second issue was the clause allowing the minister to reverse regulations and decisions by the council.

He said he supported the council being regarded as a juristic person, held responsible in law for the decisions it took, but at the same time the minister was given the power to change and veto decisions the council had taken and these positions were not reconcilable.

"I have seen the end of the tunnel that is being described in this draft bill and it is dark," Professor Folb said.

"It is a Third World trap."

The World Health Organisation had warned repeatedly against issues introduced in the draft bill.

The Star ... Thursday September 18 1997

Zuma's medicine bill is a bitter pill to swallow

Star 18/9/97 (96)

Strong opposition to draft laws that would give minister sweeping powers

By Jovial Rantao
Cape Town

The pharmaceutical industry, big business, six political parties and the Medicines Control Council (MCC) have rejected Health Minister Dr Nkosazana Zuma's draft legislation aimed at reducing the price of drugs through parallel importation and legislated generic substitution.

MCC chairman Professor Peter Folb said his organisation, which has had thorough consultation with Zuma, was unhappy that the Medicines and Related Substances Control Amendment Bill would give the minister sweeping powers.

"The MCC cannot understand why the minister seems to have so little confidence in the council that she requires extraordinary powers to enable her to overrule, ignore or reject the recommendations made by the council and to ask Parliament to endow her with sweeping powers which can result in unilateral action by her whenever she wishes to use it," Folb said.

The MCC believed that some clauses in the legislation would harm the medicine control process and set the scene for unacceptable double standards which would be applied to medicine registration and control.

Folb said if the bill was adopted unchanged, the stage would be set for immediate and continued conflict between the MCC and Zuma.

He accused the health department of reneging on agreements it had made with the MCC on the legislation and requested that the bill should be held back until several clauses had been deleted.

In a joint statement, the Democratic Party, the National Party, the Inkatha Freedom Party, the Pan Africanist Congress and the African Christian Democratic Party said evidence against the bill was strong and called on Zuma to withdraw the bill.

The parties said Zuma should re-enter into a process of negotiation and consultation with the MCC and other role players to provide medicine control measures that were in the best interests of the country and its people.

The Dispensing Family Practitioners' Association said the bill smacked of "Gestapo legislation" in the extensive powers it gave the minister.

Health reforms will go ahead — Zuma

BD 19/9/97 (96)

Jacob Dlamini

CAPE TOWN — Health Minister Nkosazana Zuma hit back at critics of her proposed health reforms yesterday and said the legislation would go ahead despite opposition and threats of legal action from the pharmaceutical industry.

Zuma said she had made enough compromises to accommodate stakeholders' concerns. She said she would have been surprised if the bills, which seek to improve access to health care by lowering the price of drugs through generic substitution, parallel importation and international tendering, had been accepted without opposition.

Zuma said she hoped the bill, which is before Parliament's health committee, would be put to the National Assembly when it began its fourth quarter next month.

Zuma dismissed accusations made by Medicines Control Council chairman Peter Folb that the legislation would give her unfettered powers to act without the advice of the council.

She said the council would retain its powers to register and check on the efficacy of drugs. But the legislation would give her the power to initiate regulations if it was deemed to be in the national interest. This, she said, would be accompanied by discussions with the council.

Zuma rejected Folb's claims that provisions in the bill making the council a juristic person would expose it to legal challenges. She said the provisions were designed to make the council accountable for the decisions it took.

Health director-general Olive Shisana also rejected Folb's claims. Shisana said Folb's complaint that the legislation would give Zuma extensive powers to overrule the council was unwarranted as the minister already had original powers in the existing laws.

Shisana said there were several countries, including Canada, that had drug regulatory authorities whose decisions were treated as recommendations for approval by their respective ministers.

National Association of Pharmaceutical Manufacturers executive director Barney Sachs told the committee some of the amendments proposed in the bill would negatively affect the quality and safety of drugs. He said generic substitution would violate intellectual property rights and deny business the chance to get good returns on its investment. Sachs said this would lead to lengthy legal and constitutional battles.

Meanwhile, the Inkatha Freedom Party called for the bill to be withdrawn until further debate on health financing and regulation. Spokesman Ruth Rabinowitz said the bill was authoritarian and would place the licensing of health professionals under the control of the minister. She said generic substitution would deny patients the right to choose medicines.

Defiant Zuma won't budge on controversial health bills

Star 19/9/97 (96)

By Jovial Rantao
Political Correspondent

Cape Town – On a day on which opposition to her controversial health bills grew, Health Minister Nkosazana Zuma remained adamant that the three pieces of legislation – aimed at reducing the price of drugs and improving access to health care – would become law.

Zuma said she expected the Medicines and Related Substances Control, the Medical, Dental and Supplementary Health Service Professionals and the Pharmacy Amendment bills to become law before Christmas.

The minister yesterday attended the public hearing on the Medicines and Related Substances Control Amendment Bill in Parliament.

She said the strong opposition to the Medical and Related Substances Amendment Bill, discussed during a hearing of Parliament's Health Committee yesterday, had been expected.

"I didn't expect them to sing hallelujah ... I expected a fight. I have compromised enough and the bill will be taken through the normal (parliamentary) procedures. I have no intention of withdrawing the bill," Zuma said.

She expected the bills to be approved by Parliament before the Christmas break.

Zuma denied allegations by the Medicines Control Council and other stakeholders that she was interested in allocating enormous power to herself.

The MCC has submitted to the committee that the legislation would endanger the lives of South Africans because Zuma had powers to override the council's decisions.

Health director-general Dr Olive Shisana said concerns for the safety of patients was unfounded and that allegations that Zuma had extensive powers to overrule the MCC were unwarranted.

The National Association of Pharmaceutical Manufacturers criticised the Medicines and Related Substances Amendment Bill for being vague in certain clauses.

Barney Sachs, executive director of the NAPM, objected to the clauses which gave the minister the power to upturn the Patents Act without recourse to Parliament and called for its deletion.

The NAPM was opposed to any form of price control, as suggested in the bill. Healthy competition was a more effective way to drive prices down, Sachs added.

Dr Norman Mabasa of the National Convention for Dispensing Doctors said the Government should not regulate dispensing doctors and called for the scrapping of VAT on medicines as a way of reducing the cost of health care.

The hearings on the bills will be concluded today.

Zuma adamant on trio of health bills

(96) CT 19/9/97

POLITICAL STAFF

ON a day when opposition to her controversial health bills grew, Health Minister Dr Nkosazana Zuma remained adamant that the three pieces of legislation — aimed at reducing the price of drugs and improving access to health care — would become law.

FIRM: Nkosazana Zuma

Zuma said she expected the Medicines and Related Substances Control, the Medical, Dental and Supplementary Health Service Professional and the Pharmacy Amendment bills to become law before Christmas.

Zuma attended the public hearing on the Medicines and Related Substances Control Amendment Bill in Parliament yesterday.

She said the strong opposition to the bill, which was discussed during a hearing of Parliament's Health Committee yesterday, was expected.

Among the bill's opponents was Dr Norman Mabasa, of the National Convention for Dispensing Doctors, who said the government should not regulate dispensing doctors and called for a scrapping of Value-Added Tax on medicines as a way of reducing the cost of health care.

The National Association of Pharmaceutical Manufacturers (NAPM) criticised the bill for its lack of detail and for being vague in certain clauses.

Mr Barney Sachs, executive director of the NAPM, objected to the clauses which gave the minister the power to overturn the Patents Act without recourse to Parliament, and called for deletion of the clauses.

Sachs said the elimination of a system of bonuses and samples to doctors and pharmacists would increase the costs of Schedule 0 drugs, which can be bought in supermarkets. "We believe that Schedule 0 products should be exempt from such regulation and a provision built in that these products cannot be used as incentives for the sale of other medicines in pharmacies. Allowances should be made for a volume based non-discriminatory pricing system," Sachs said.

The NAPM was opposed to any form of price control, as suggested in the bill, because it would interfere with free market practices. Healthy competition was a more effective way to drive prices down, Sachs added.

Well-known patent lawyer Dr Tim Burrel urged the committee to delete Section 15(c) of the bill because it would violate conventions signed with the World Trade Organisation. He said if the bill was passed unchanged, "we would look like a bunch of incompetents".

But the minister remained adamant: "I didn't expect them to sing Hallelujah ... I expected a fight.

"I have compromised enough and the bill will be taken through the normal (parliamentary) procedures. I have no intention of withdrawing the bill."

Zuma denied allegations by the Medicines Control Council (MCC) and other interested parties that she was interested in allocating enormous power to herself.

Health director-general Dr Olive Shisana said yesterday clauses in the bill clearly ensured that the minister would have to approve regulations relating to imported medicines when there was complete agreement with the MCC.

Shisana said concerns for the safety of patients was unfounded and that allegations that Zuma would have extensive powers to overrule the MCC were unwarranted. The hearings on the bills will be concluded today.

● If measures were introduced to identify medicines sold to the state, tracing them back to government stores would be relatively easy and proof of theft and possession of stolen medicines would be a mere formality, the Portfolio Committee on Health was told by the Association of Pharmaceutical Wholesales and Distributors.

Mr Peter Hodes, SC, for the association, told the committee the stated aim of the proposed legislation was to prevent the entry of stolen medicines into the market.

However, none of the envisaged benefits would necessarily derive from the proposed legislation. Instead it would have a devastating effect on prices and on wholesalers and small pharmacies in the disadvantaged communities. On the other hand, the asssociation had been able to get substantial discounts on medicines and could pass on the savings to outlets.

Doctors, patients take to streets to protest Zuma dispensing plan

ARG 20/9/97 (96)

Durban – Health Minister Nkosazana Zuma came under attack when about 400 doctors and their patients staged a protest march through the Durban city centre yesterday.

Protesting against a proposed law that would prevent doctors from dispensing medicines, the group chanted "Down with Zuma" as they made their way to the City Hall.

Carrying posters with slogans that included "Dispense with Zuma", "Zuma's health policy is sick" and "We doctors will defy Zuma's dispensable laws", the group handed a memorandum to Dr Olaf Baloyi from the provincial health department.

The march was organised by the National Council on Dispensing, which was formed a year ago when Dr Zuma initiated laws to prevent doctors from dispensing medicines.

Dr Sarwan Bugwandin of the Family Practitioners Association said the march was the first phase of a mass action programme which would include a defiance campaign and a nation-wide petition.

Doctors have also vowed to take the minister to court if the bill is passed.

"We are not against the principal of health for all but we are against the minister's high handedness and her lack of consultation," Dr Bugwandin said. – Own Correspondent

Cautious support for Zuma's health reforms

Jacob Dlamini

(96) BD 26/9/97

CAPE TOWN — The Interim Pharmacy Council expressed support for Health Minister Nkosazana Zuma yesterday but said it believed there would be compromises made in the minister's proposed reforms to address the concerns of the pharmaceutical industry.

Registrar Jan du Toit said the council supported any mechanisms designed to bring down the price of medicines, provided adequate steps were taken to ensure the safety and effectiveness of drugs.

Du Toit said the council supported principles such as the introduction of parallel importation to force pharmaceutical companies to lower their prices; making generic substitution mandatory in order to give patients the choice of using cheaper medicines; and prohibiting sampling and bonusing, two systems by which doctors and pharmacists dispense particular brands of medicines.

He said that while the principles underlying the bills would not change, he believed Zuma would address the problems associated with the wording and the drafting of the new legislation.

Du Toit's comments came in the wake of a meeting between Zuma and representatives of the pharmaceutical industry in Pretoria earlier this week.

According to Zuma's spokesman, Vincent Hlongwane, the meeting addressed issues such as the draft health legislation, the theft of medicines from state depots and SA's role as the health sector co-ordinator for the Southern African Development Community.

Hlongwane said the two parties had "agreed to disagree" on the legislation after Zuma rejected calls by the pharmaceutical industry to withdraw her bills from Parliament to allow for further discussion.

He dismissed claims that the draft legislation violated intellectual property rights, saying the health department had checked all relevant laws and was convinced it was on firm ground.

Drugs Bill 'poses a threat' to SA health

(96)

CAS St LEGER

ST 28/9/97

THE head of the Medicines Control Council, Professor Peter Folb, has warned that South Africa's health system is in danger of falling into a "third-world trap".

Addressing public hearings in Cape Town on September 17, Folb said aspects of the Medicines and Related Substances Control Amendment Bill — due to go before Parliament at the end of October — were "thoroughly unsound".

He said the Bill was seriously flawed because it would allow the importation of cheap drugs — which could threaten people's safety, and violate international patent rights — and granted overriding powers to the Minister of Health, Nkosazana Zuma.

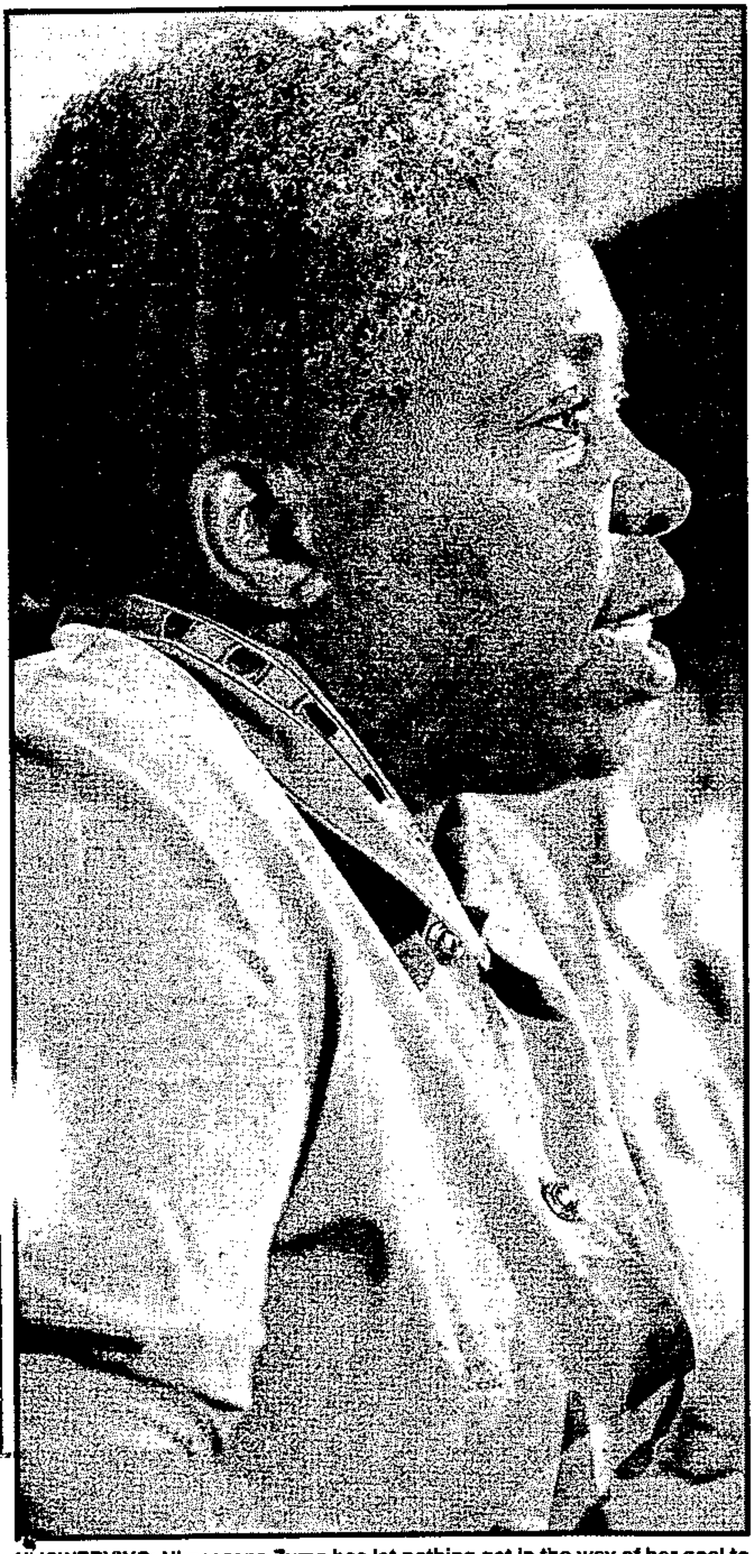
"I am afraid that the minister has received poor advice and the result, in part, is ridiculous," said Folb.

The country was in danger of falling into a "third-world trap".

"The confidence of the people in health care in the country depends in no small part on confidence in the quality of medicines," he said.

"If the essential flaws in this Bill are applied, international confidence in our health system and our medicines will be lost on the same day."

● The Zuma Wars: p28



UNSWERVING: Nkosazana Zuma has let nothing get in the way of her goal to provide health care to South Africa's poor majority

A juggernaut called Zuma

(96) ST 28/9/97

The minister of health stirs up passionate emotions no matter what she does, writes CAS St LEGER

HEALTH Minister Dr Nkosazana Zuma has not lost a single battle since she moved into her offices in the Civitas building in Pretoria in May 1994, the ANC's health plan tucked under her arm as her blueprint and her Bible.

She did, admittedly, lose out to Winnie Madikizela-Mandela for the chairmanship of the ANC Women's League earlier this year. But that was a minor skirmish.

She has faced more flak than any other cabinet minister. And, unlike Winnie, she has the backing of President Nelson Mandela, who declared last weekend: "I will never fire her."

Like a juggernaut, she has rolled over most obstacles — although, on occasion, she has been forced to make some minor tactical retreats before plunging headlong into the fray once again.

And, whatever her critics might say, her quest to change the face of South Africa's health services — skewed by decades of apartheid and colonialism — is succeeding.

Her zeal has earned her passionate friends and equally passionate enemies.

Zuma's critics say she is autocratic, lacks judgment and is often too quick off the mark.

Her admirers praise her uncompromising spirit in facing up to the big guns — such as the multinational pharmaceutical companies — in her quest to change the health system to meet the needs of the poor.

But in her struggle she has appeared to ignore the finer details of her plans — and the costs.

Hospitals and clinics were left to work out for themselves how to pay for free primary health care and free abortions. Her priority has been primary health care and preventive medicine — to save the lives of thousands of children who might have died from untreated diarrhoea, for example — rather than expensive treatments like organ transplants.

She has won the support of ordinary citizens, some of whom now have access to health care for the first time. And the medical aid industry backs Zuma's attempts to contain prices, particularly those of drugs.

Her victories since 1994 include free basic health care; free abortion; the vaccination of almost all South African children against measles and polio; 350 new clinics and the upgrading of 2 298 more; a feeding scheme for 4,4 million schoolchildren; foreign doctors to fill the rural vacuum; and condoms for male prisoners.

On the negative side, there was the fiasco of the AIDS-awareness musical *Sarafina 2*, which cost the taxpayer R14-million; concern about using Cuban doctors, few of whom could speak English, let alone any indigenous languages; her restraints on top-line treatments like heart transplants; budget cuts for leading hospitals already reeling under hugely increased patient loads and massive theft; her criticism of young doctors who balk at her plans for compulsory community service; clauses in two health Bills that will give her authoritarian powers to override statutory bodies; and the embarrassment of her sales pitch on the merits of the "AIDS drug" Virodene.

Although her battles have caused the greying of her hair in the past year, Zuma is now poised for her most determined battle yet — to push three new health Bills through Parliament that will have a profound impact on health care. They are:

- The Medicines and Related Substances Control Amendment Bill;
- The Medical, Dental and Supplementary Health Services Profession Bill; and
- The Pharmacy Amendment Bill.

DRAWING THE BATTLE LINES

THESE are the wars that Health Minister Dr Nkosazana Zuma hopes to fight and win:

PATENT WAR

THE Medicines and Related Substances Control Amendment Bill will allow the import of drugs at prices cheaper than those available locally.

AIM: To force down the prices of medicines, particularly brand-name drugs, by as much as 20 percent, through increased competition.

SUPPORTERS: The ANC, and the health insurance and medical aid industry.

OPPONENTS: The multinational drug companies and large local producers falling under the Pharmaceutical Manufacturers' Association. They say Zuma's plans would undermine the rights of patent holders as outlined in the Trade Related Aspects of Intellectual Property Rights and Trade in Counterfeit Goods Agreement, of which South Africa is a signatory.

EVALUATION: She will probably get the Bill through, but she may have to back down on the provision giving her the right to side-step the international patents agreement.

International producers operating in South Africa have until October 6 to lodge objections.

In the meantime, through the Pharmaceutical Manufacturers' Association, court action or disinvestment threaten.

Zuma's drugs policy adviser, Dr Wilbert Bannenberg of the World Health Organisation, shrugs off threats to disinvest.

He calculates that if the multinational drug companies left and jobs were lost, R385-million could be saved by buying cheaper drugs on the world market.

There is also a threat of counterfeit drugs flooding into the country — 60 percent of the drugs used in Africa are counterfeit.

DRUGS WAR

THE Medicines and Related Substances Control Amendment Bill will allow the health minister to enforce the use of cheaper "generics" — drugs that are virtually identical to trademarked drugs, for which the 20-year patent has expired.

AIM: Calculated savings of R750-million a year.

SUPPORTERS: Zuma's adviser, Bannenberg, the ANC, and qualified support from the Pharmacy Council.

OPPONENTS: Multinational drugs companies and the Pharmaceutical Manufacturers' Association. The Medical Association of SA and the Medicines Control Council do not oppose the use of generics, but they oppose Zuma's intention to enforce their use and her powers to override Medicines Control Council decisions.

EVALUATION: Under the new legislation, the use of generics will be enforced, except where the doctor writes "no substitution" on the script; the patient refuses a substitute; the drug is on the Medicines Control Council list of 100 non-substitutable drugs; or the generic is more expensive than the brand-name drug.

The pharmacist will be obliged to tell the patient about the cheaper generic. The Pharmaceutical Manufacturers' Association says there could be complex legal tangles if a drug is substituted and the patient suffers ill effects.

INTERN WAR

THE Medical, Dental and Supplementary Health Services Professions Bill would compel medical graduates to perform a one-year term of community service (or vocational training) before they can register as doctors. The health minister could extend the term of service.

AIM: To bring medical services to disadvantaged people in areas where there are not enough doctors. And to prevent young doctors from leaving South Africa immediately after graduating.

SUPPORTERS: All the doctors' organisations support community service — but not "conscription". The Interim Medical and Dental Council supports vocational training — but says trainers are not available.

OPPONENTS: The Junior Doctors' Association and the National Interns' Alliance.

EVALUATION: Interns and young doctors argue there will be little or no supervision or training in remote postings, and they will suffer family hardships.

PHARMACY WAR

THE Pharmacy Amendment Bill will allow just about anyone to open a pharmacy, although a qualified pharmacist would have to be employed.

AIM: To cut medicine prices through competition.

SUPPORTERS: The supermarket groups.

OPPONENTS: The pharmacists.

EVALUATION: The director general of health, instead of the Pharmacy Council, would be given powers to grant or refuse licences.

Doctors would be licensed to dispense medicines where there is no pharmacy.

TOBACCO WAR

THIS battle is about curbing cigarette consumption by restricting smoking in public places and banning tobacco advertising.

AIM: To stop young people from lighting up, and persuading others to quit.

SUPPORTERS: The anti-smoking lobby, the Cancer Association of SA, and the entire medical and health sector.

OPPONENTS: Cigarette smokers and the tobacco industry.

EVALUATION: Zuma has South Africa stubbing out stompies in restaurants, offices and shops. She has also achieved her goal of doubling the price of a pack of 20s — helped by the tobacco industry's policy of slipping in its own price hikes under cover of Zuma's annual Budget increases.

In addition, she has enforced a ban on advertising cigarettes on television, and introduced health warnings on cigarette packets and print adverts.

Zuma appears to be winning the war, despite vigorous opposition from the likes of Johann Rupert, the chairman of the powerful Rembrandt empire, who lashed out at her for encouraging the smuggling of cigarettes into South Africa.

The liquor industry has fared better. Zuma says the occasional drink is good for you.

HEALTH INSURANCE WAR

THIS battle has yet to be fought, but Zuma says plans are ready to come off the drawing board.

AIM: To provide health care to the millions of South Africans who do not have medical aid, financed by those who can afford to pay.

OPPONENTS: Likely to be those who will feel they are being unfairly penalised by having to support those who cannot pay.

SUPPORTERS: Likely to be those who are not members of medical aids.

EVALUATION: An early suggestion was a "payroll" tax of five percent to fund the scheme. The implications are that free choice for tomorrow's private patient may prove to be beyond the pockets of most people.

(a) How many cases of malaria were reported in South Africa in 1996 as compared to 1995 and (b) which areas had been declared as high risk malaria areas in South Africa as at the latest specified date for which information is available? N1649E

The MINISTER OF HEALTH:

(a) In 1996, 10 455 cases of malaria were reported in South Africa as 5 992 cases in 1995.

(b) The following areas have been declared as high risk malaria areas as on 1 August 1997:

KwaZulu/Natal

1. Hiabisa
2. Ingwavuma
3. Ubombo

Mpumalanga

1. Albertsnek
2. Block C
3. Figtree
4. Klipspruit
5. Mbangwane
6. Mbuzini
7. Naas
8. Nelspruit town
9. Steenbok

Northern Province

High risk areas are North Eastern of the northern region and the eastern side of the Lowveld.

The specific districts are:

1. Dnazini,
2. Giyani,
3. Letaba,
4. Luiekani,
5. Malamulele,
6. Mapulaneng,
7. Messina,
8. Mhala,
9. Mutale,
10. Namakgale,
13. Phalaborwa,
12. Thohoyandou,
13. Tshitale,
14. Vuwani.

Source: Provincial Departments of Health, August 1997

Private/public hospitals: number of hospital beds

*19. Dr S J GOUS asked the Minister of Health: [Written Question No 948]

What was the total number of hospital beds in (a) private and (b) public hospitals in each of the provinces in (i) 1995 and (ii) 1996? N1650E

The MINISTER OF HEALTH:

Province	Total number of beds in:			
	(a) Private Hospitals		(b) Public Hospitals	
	(i) 1995	(ii) 1996	(i) 1995	(ii) 1996
1. 1 Military Hospital	0	0	386	386
2. 2 Military Hospital	0	0	236	236
3. 3 Military Hospital	0	0	180	153
4. Western Cape	*4 857	*4 857	14 762	14 402
5. Free State	2 152	2 216	7 267	7 183
6. KwaZulu-Natal	3 107	3 107	24 884	25 033
7. North West	*722	*722	7 905	7 905
8. Eastern Cape	1 199	1 199	17 416	17 416
9. Northern	196	196	10 299	10 430
10. Mpumalanga	1 353	1 353	4 427	4 427
11. Gauteng	14 594	14 594	19 967	19 733
12. Northern Cape	*449	*449	2 206	1 741
Total	28 629	28 693	109 935	109 045

* Information from the National Department of Health and not the Province

Source: Provincial Health Departments, 1997

Dentists/phamacists/specialists/general practitioners in practice

*20. Dr W A ODENDAAL asked the Minister of Health: [Written Question No 964]

What percentage of (a) dentists, (b) pharmacists, (c) specialists and (d) general practitioners practised (i) in the private sector, (ii) full-time in the government sector, (iii) in the private sector, but rendering services in the government sector, and (iv) in the government sector, but also part-time in private practice, in (aa) 1995 and (bb) 1996? N1666E

The MINISTER OF HEALTH:

	(aa)				(bb)			
	(i)	(ii)	(iii)	(iv)*	(i)	(ii)	(iii)	(iv)*
(a)	75.3%	17.0%	2.9%	3.0%	75.4%	17.3%	2.9%	3.7%
(b)	73.3%	15.0%	0.75%	2.6%	75.3%	13.3%	0.75%	3.3%
(c)	45.7%	38.0%	34.5%	2.5%	49.8%	37.8%	32.1%	2.0%
(d)	42.7%	27.0%	15.7%	7.3%	45.7%	25.0%	13.8%	6.2%

*Only those for whom authority has been granted (Limited Private Practice or Remunerative work outside employment in the Public Service in accordance with PSSC. Chapter Moonlighting cannot be determined in percentage.

Sources: Representative Association of Medical Schemes (RAMS), Personnel and Salary System (PERSAL), Department of Health (DOH), South African Medical Services (SAMS), Provincial Health Departments, Interim Medical and Dental Council of SA, Interim Pharmacy Council of SA.

the Commission. The Commission independent and separate from any party, government, administration, or any other functionary or body directly or indirectly representing the interests of any such entity.

The Department does not have any authority to take any steps following the Auditor-General's findings concerning the financial affairs of the Commission.

However, the Director-General and the Chief Executive Officer of the Commission work in close co-operation with each other and constantly discuss matters relating to the Commission. The Department of Justice is rendering every possible assistance required by the Commission to fulfill its functions in compliance with the prescripts applicable to the Commission.

(2) In my view the Commission and the Chief Executive Officer of the commission render an outstanding service and, there is no reason for any action on my side. Both the Department of Justice and the Chief Executive Officer endeavour that all prescripts are complied with.

*14. Dr B L GELDENHUYS – Foreign Affairs.† [Question standing over.]

Pharmacies monitored for counterfeit drugs

*15. Mr M F CASSIM asked the Minister of Health:

(1) Whether her Department or any State agency consistently monitors pharmacies with a view to establishing whether such pharmacies keep counterfeit drugs in stock; if not, why not; if so, (a) how and (b) what are the further relevant details;

(2) whether she or her Department has ascertained that only authentic medicines are available from retail and government outlets; if not, why not; if so, what are the relevant details? N1968E

The MINISTER OF HEALTH:

(1) Routine inspections of pharmacies and other facilities where medicines are manufactured, kept or stored, are performed in terms of the Pharmacy Act and the Medicines and Related Substances Control Act.

Inspections by the Pharmacy Council are done independently of the Department of Health, utilising the Council's own inspectors.

The Director-General: Health, appoints inspectors in terms of the provisions of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) for the enforcement of the Act.

The purpose of the inspections is to ensure compliance with the requirements of the Medicines Control Act, the Foodstuffs, Cosmetics and Disinfectants Act and the Pharmacy Act.

The Medicines Control Council also makes use of a firm of private investigators, whose personnel assist with particularly difficult inspections.

Counterfeit medicines identified are seized and sent for analysis, and criminal charges laid against the suspects in terms of the Medicines Control Act.

(2) The Medicines Control Act, prohibits the sale of unregistered medicines. The Medicines Control Council evaluates each application for registration of a medicine for safety, efficacy and quality. The inspectors, inspect all applicants, manufacturers, laboratories and wholesalers on a regular basis to assess compliance with current Good Manufacturing Practice (GMP), Good Laboratory Practice and Good Wholesaling or Distribution Practice.

Random samples of medicines (final products and raw materials) are taken and tested at an independent laboratory for compliance with the specification for identity, assay and other parameters.

Medicines available on the market may only be manufactured in accordance with the registration dossier, as approved by Council. Regular compliance inspections, where this is verified, are performed by the inspectors.

The combination of GMP inspections, compliance inspections and testing of samples result in assessment and assurance that only authentic medicines should be available in the country.

When any counterfeit medicine is identified, immediate action is taken to initiate a full investigation and withdrawal of the product from the market. The World Health Organisation is further informed of the identified counterfeit products. Once again, where a case can be made, criminal charges are laid.

Petrol "routers"

*16. Mr M F CASSIM asked the Minister of Minerals and Energy:

(1) Whether his Department had uncovered the existence of so-called "routers" who offer to supply petrol to recognised dealers at considerably lower cost than such dealers will be able to obtain petrol from recognised suppliers; if not,

(2) whether he or his Department will consider undertaking an investigation to establish whether such a practice exists; if not, why not; if so, what are the relevant details? N1969E

The MINISTER OF MINERALS AND ENERGY:

(1) No

(2) Yes. The Service Station Rationalisation Plan which is a voluntary agreement between the Department of Minerals and Energy, the organised service station industry and the oil companies promotes the orderly and economic distribution of fuel and it addresses such practices. Should the relevant information be made available, an investigation could be considered.

Maluti magisterial district: pensions

*17. Mr G Q M DOIDGE asked the Minister for Welfare and Population Development:

(1) Whether she or her Department took any steps to ensure that pensioners in the Maluti magisterial district of the Eastern Cape received their pensions after the Eastern Cape government stopped payment on all First National Bank cheques payable to pensioners in Maluti; if not, why not; if so, what steps;

(2) whether, with reference to a certain press report, a copy of which has been furnished to her Department for the purpose of her reply, with the purport that cheques to the value of more than R1,5 million had been stolen from the Eastern Cape government, she or her Department has taken any steps to inform pensioners that these cheques had been stolen; if not, why not; if so, what steps;

(3) whether she will furnish an explanation in regard to the theft of the said cheques; if not, what is the position in this regard; if so, what are the relevant details;

(4) whether she or her Department intends taking any steps aimed at preventing a recurrence of such thefts; if not, why not; if so, what steps;

(5) what is the exact amount involved in the theft of these cheques? N1970E

The MINISTER FOR WELFARE AND POPULATION DEVELOPMENT:

(1) Yes, a total number of 25 cheques were stopped at the banks and cheques to the value of R940 were re-issued. This amount includes the payment due to pensioners for a two month period, but excludes back pay. These cheques have been re-issued, because of their geographical location. These pensioners will receive their cheques during the September pay period,

(2) no, no incidences of stolen cheques have been reported in the Eastern Cape Province, however, the Department needs to obtain a more complete picture and is in the process for further investigation by the Department and to ensure whether a criminal case has been opened and by whom,

(3) no, only when more information is available,

(4) yes, the Department is presently investigating the media report;

(5) nil.

the NCPS secretariat.

The focus of the week would be all aspects of the NCPS, "in particular, the practical steps that have been taken in tection Bill, Criminal Procedure Amendment Bill – which amends the bail laws – and National Prosecuting Authority Bill.

Medicine bill row deadlocked

ARG 1/10/97 (96)

POLITICAL CORRESPONDENT

A meeting between Health Minister Nkosazana Zuma and the pharmaceutical industry failed to resolve differences over the minister's medicine control reform legislation.

Industry representatives asked for the bills to be withdrawn and redrafted from scratch, a plea which met with outright refusal by the health ministry.

"We are going ahead as planned. We agreed to disagree," a ministerial representative said.

At the meeting, the ministry asked the industry to draw up regulations in anticipation of the legislation being passed. The ministry said the regulations should be forwarded to it by the second week of next month, to prepare for a meeting in early December.

In a joint statement at the end of the spring session, the Democratic Party, Freedom Front, Inkatha Freedom Party, National Party and Pan Africanist Congress said they refused to be part of rubber-stamping the bills.

The opposition parties urged the department to enter into further discussions with key roleplayers in the health industry.

Health industry to oppose bills at hearing

CT 6/10/97 (96)

OWN CORRESPONDENT

INTERNATIONAL pharmaceutical companies are expected to voice their opposition to at least two of the three controversial health bills when they table their submissions today during public hearings hosted by Parliament's health committee.

Most have voiced opposition to the Medicines and Related Substances Amendment Bill, which allows for parallel importing of drugs, and the Pharmacy Amendment Bill, which provides for lay ownership of pharmacies.

Representatives from some of the companies have met Health Minister Dr Nkosazana Zuma to discuss their concerns. The meeting failed to resolve differences.

At the meeting, the health ministry turned down the industry's plea that the bills should be withdrawn and redrafted.

The three bills have received a mixed response from different stakeholders.

Major opposition political parties have voiced their opposition to them and have urged the department to enter into further discussions with key role players in the health industry.

Despite the opposition, Zuma has remained adamant that the bills — aimed at reducing the price of drugs and improving access to health care — will become law.

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Health-bills fight continues

By Jovial Rantao
Political Correspondent

Cape Town – International pharmaceutical companies are today expected to voice their opposition to at least two of the three controversial health bills when they table their submissions during public hearings hosted by Parliament's Health Committee.

Most of the companies have expressed opposition to the Medicines and Related Substances Amendment Bill, which allows for parallel importation of drugs; and the Pharmacy Amendment Bill, which provides for lay ownership of pharmacies.

Representatives from some of the companies have met Health Minister Dr Nkosazana Zuma to discuss their concerns. The meeting failed to resolve differences about her legislation on medicine-control reforms.

At the meeting, the Health Ministry turned down the industry representatives' plea that the bills should be withdrawn and redrafted.

The three bills have received a mixture of responses from different "stakeholders". Major opposition parties – the National Party, the Inkatha Freedom Party and the Democratic Party – have voiced their opposition to the bills and are expected to oppose them when they are tabled in Parliament.

The opposition parties urged the department to enter into further discussions with "key role players" in the health industry, to achieve the goals of lowering the cost of medicines to the private sector, while protecting people's safety and freedom of choice.

Despite the opposition, Zuma has remained adamant that the three pieces of legislation – aimed at reducing the price of drugs and improving access to health care – would become law.

The debate on the three health bills and debates on Labour Minister Tito Mboweni's Basic Conditions of Employment Bill are expected to be the major focal point during Parliament's fourth quarter, which starts today.

Star 6/10/97

Merck 'may quit SA' over drugs bill

(9b) BD 7/10/97

Wyndham Hartley

CAPE TOWN — Merck, the major US pharmaceutical corporation which has already put a R50m investment on hold, says it could withdraw its operation in SA if Health Minister Nkosazana Zuma's medicine and related substances bill is approved by Parliament in its present form.

US patent lawyer Charles Caruso and Donald de Korte, CE of Merck's SA operation Merck, Sharpe & Dohl (MSD), speaking with the full backing of the International Federation of Pharmaceutical Manufacturers, told Parliament's health committee yesterday that if the legislation was passed it could also result in SA being denied access to any new anti-AIDS drugs that might be developed because of the lack of patent protection.

De Korte said MSD would have to "review its involvement in this country" if the legislation was not altered. He insisted that he was not threatening the committee or the health ministry but was simply "trying to make you see how serious this is".

He said it would be a major negative signal to foreign investors. It was a violation of the international agreement on the trade-related aspects of intellectual property (Trips) which gives the patent owner the exclusive right to stop third parties from importing the patented invention, including the power to stop parallel importation.

De Korte said singling out only the pharmaceutical industry was also a violation of the Trips nondiscrimination provisions and a provision in the international agreement designed to protect pharmaceutical test data from unfair commercial use.

ZUMA

"These flagrant violations of the Trips agreement, whilst specific to the pharmaceutical industry in this instance, cannot augur well for SA's newfound respectability and credibility within the global economic arena.

"It will inevitably send the wrong signals to existing and potential foreign investors of stature and will place SA in association with the countries of

Continued on Page 2

Merck

(9b)

Continued from Page 1

BD 7/10/97

the world that are the most egregious patent law violators," De Korte said.

He said the law would drive research-based pharmaceutical multinational companies from the country and place South Africans at the mercy of foreign interests because parallel importation "benefits neither patients nor governments; only the parallel importer is financially enriched".

De Korte said there were huge markups in the distribution of medicines in SA of more than 80%, while in the US they were only 20%. These margins should be lowered through increased competition.

Noel Dolman, speaking on behalf of 12 pharmaceutical companies belonging to the American Chamber of Commerce in SA, joined the others in challenging Zuma's contention that medicines were supplied to SA at a high cost. He said the state as a purchaser received medicines at prices among the lowest in the world.

The problem was that almost half of the drugs purchased by the state were stolen "and this is a major reason why quality medication is not available to a greater number of the population".

The legislation was "extremely worrisome" and would "compromise SA's compliance with the World Trade Organisation and its commitment to the protection of intellectual property rights". This was a commitment which the SA government had given at the recent meeting of the US-SA binational commission.

The Star ... Tuesday October 7 1997

Cheap drugs will take jobs, Zuma warned

Star 7/10/97 (96)

Pharmaceutical giants tell Parliament's health committee there is big money at stake, and that the world is watching

By Jovial Rantao
Cape Town

Pharmaceutical multinationals have warned that the approval of draft legislation enabling Health Minister Dr Nkosazana Zuma to import cheaper medicines could lead to closure of factories, the loss of thousands of jobs and a drop in foreign investments.

In their submission before Parliament's health committee, the companies argued that parallel importation was not necessary because the price of medicines in the public sector was among the lowest in the world.

They argued that the distribution system of medicines, described as inefficient and uncompetitive, was responsible for the markup of up to 82% to the pharmaceutical manufacturers' price. Theft from public hospitals also contributed to the high cost of medicines.

Emphasising that he was not threatening the Government, Dr Donald de Korte, chief executive officer of MSD, a Gauteng-based pharmaceutical company, warned that if the Medicines and Substances Control Amendment Act was passed, his company would be among those who would consider disinvesting from SA.

That, he warned, could lead to the loss of jobs for 17 000. He said he had kept on hold a R50-million investment to upgrade MSD's manufacturing facilities, pending the approval or rejection of the bill.

De Korte said the proposed legislation was a threat to the future of multinational investment and participation in the South African economy.

He said that if the intention of the Ministry of Health and the Government was to restrict the proposed amendments to the pharmaceutical industry and not to apply the same principle to other industries, then the proposed legislation was discriminatory, unconstitutional and a violation of SA's obligation under international trade agreements.

De Korte submitted that while the intention of the draft legislation was to ensure the provision of affordable medicines, the longer-term consequences of removing the rights of the research-driven pharmaceuticals multinationals to the protection of their patents in SA would have the opposite effect.

The American Pharmaceutical Industry in South Africa, representing 12 companies with a combined revenue of R705-billion, said the draft legislation was worrisome as it appeared to abrogate all patent law and the basic and essential patent rights of pharmaceutical companies, and allowed the minister of health to expropriate the rights to patented medicines.

Noel Dolman, a representative of the US companies, said the passage of the legislation would compromise SA's compliance with the World Trade Organisation and its commitment to the protection of intellectual property rights.

"The US business community is watching closely for the broader trade and investment implications raised by this legislation," Dolman said.

ANC MP Mtutuzeli Mpehle said the firms were selective in their presentations by not referring to a clause in the WTO Tripps Agreement which allowed for parallel importation.

Drugs bill will not make firm quit SA

BD 9/10/97 (96)

Shareen Singh

A PHARMACEUTICAL company MSD SA, a subsidiary of US-based Merck, has given the assurance that it will not quit SA, no matter what the final shape of the controversial Medicines and Related Substances Bill.

US patent lawyer Charles Caruso said yesterday Merck would not withhold any new AIDS cure or treatment, irrespective of whether the SA government enacted the bill.

He said the issue of section 15 (c) of the Medicine and Related Substances Control Amendment Bill, which Merck and the international pharmaceutical industry was challenging, were separate issues. Section 15C would remove patent protection previously enjoyed by major drug companies.

Caruso also said that Merck "will not quit SA" but review its investments in the light of "what impact the law will have on our business. We will have to decide on whether we have a bigger or smaller operation in SA and explore other options."

He said most countries including Japan, Korea, the European Union and most recently Australia, had adopted positions on patent protection "opposite to the stance being adopted by the SA government".

Caruso addressed the parliamentary standing committee on health this week on behalf of Merck and the International Federation of Pharmaceutical Manufacturers' Association in the hope of persuading MPs to amend the bill.

He said section 15 (c) was a violation of the international agreement on the trade-related aspects of intellectual property which gives the patent owner the exclusive right to stop third parties from importing the patented invention, including the power to stop parallel importation.

The bill in its current form would remove economic incentive for multinationals to be based in SA.

Caruso accepted that patented medicines were more costly than generics, but the companies which held the patents had no control over pricing of medicines in other countries.

FLY IN THE OINTMENT: Health Minister Nkosazana Zuma

Picture: NICKY DE BLOIS

ST 12/10/97

Ministry takes aim in Zuma's drug war

(189)

'If there are compromises to be made, they will be made'

CRAIG DOONAN

THE Ministry of Health has hinted that it may amend Minister Nkosazana Zuma's controversial Bill designed to help make medicine cheaper, but says it will not bow to pressure from drug companies who stand to lose millions.

Pharmaceutical manufacturers say the Bill contravenes international patent and trademark laws and allows parallel importing. This means it will cost less for South Africa to buy drugs from foreign countries than from local companies licensed to sell the medicine.

South Africa is a signatory to the World Trade Organisation's Trade Related Aspects of Intellectual Property Rights and Trade in Counterfeit Goods Agreement (Trips), which manufacturers say will be flouted by Zuma's law. Nico Vermaak, a patent attorney and member of the SA Institute of Intellectual Property, says he believes the powers Zuma has afforded herself in the Bill are unconstitutional "and fly in the face of the Trips agreement".

But the Health Ministry disagrees.

"The minister believes this Bill does not contravene Trips," says Vincent Hlongwane, Zuma's spokesman.

He said cabinet had backed Zuma's plans, but added that the ministry may compromise.

"If there are compromises to be made, they will be made. But the principles underlying the Bill will not change. The committee will study all the written submissions from the different parties. That process is very democratic and transparent. They will not take views from one grouping only.

"There's a perception that once the pharmaceutical company coughs, everyone should catch flu."

Hlongwane said Zuma had taken concerns about the Bill's possible violations of international agreements seriously "and we believe we're on firm ground".

"The ultimate intention is to ensure all South Africans, regardless of their social standing or economic circumstances, are able to access affordable medicine. At the moment, medicine is not affordable or accessible to the majority."

Rob Davies, chairman of the parliamentary committee on trade and industry, said concerns about the effect of the Bill on the Trips agreement should be taken seriously.

"But I'm not sure all the interested parties are necessarily the last word of authority on what will fly and what will not at the World Trade Organisation. There are a lot of special interest groups trying to put forward their own interests.

"The aim of the Health Ministry to try to secure affordable medicine for our people is an aim which is laudable and it is something international regulations ought not to be thwarting.

"What is and is not permissible in Trips needs to be weighed up in a sober way," Davies said. "A lot of people making representations are not doing anything other than reflecting their own interests in many cases.

"I don't necessarily agree with all those people going to the health committee to say what is proposed in the Bill now is in violation of Trips. I don't believe they're authorities on the subject."

Meanwhile, Vermaak warned that if Zuma's Bill was passed it could be challenged in the Constitutional Court and at the World Trade Centre.

"If this Bill is passed, we will be forced to consider our options in legal action.

"There are only two options: one is to go to the Constitutional Court; the other is for multinationals to consider whether they would request their own governments to take South Africa through the World Trade Organisation's dispute resolution procedures for violating the Trips agreement."

The Democratic Party's Mike Ellis, one of Zuma's fiercest critics, said the Bill transferred too much power from the Medicines Control Council to the minister.

"This has the potential to reduce the standard of medicine in the country," he said.

"The Bill will allow the minister a big say about what medicine can be imported and takes away this control from the council.

"You need real experts in the field of medicine, and the minister and her advisers, or the health department, could never be as effective as the council."

The European Union and the US government have backed the outcry from multinational manufacturers. They have warned that the threat to patents could lead to multimillion rand disinvestment and massive job losses.

Critics say if the Bill became law it could affect other foreign trade as it would signal that South Africa did not respect international trade agreements.

Alec Erwin, Minister of Trade and Industry, is abroad but the department's acting registrar of patents and trademarks, Craig Burton-Durham, said the Trips agreement was open to interpretation and had not yet been tested.

S' 12/10/97

(96)

Untangling the medicines tussle

ST 12/10/97

CAS ST LEGER takes a look at the issues behind the wrangle between Health Minister Nkosazana Zuma and the pharmaceutical industry.

If we can get cheaper medicines elsewhere in the world, what stops us?
South Africa has signed international agreements that prevents it from breaking patent and trademark laws. In 1994, SA signed the World Trade Organisation's Trade Related Aspects of Intellectual Property Rights and Trade in Counterfeit Goods Agreement (Trips).

Zuma's Medicines and Related Substances Control Bill proposes international tendering to buy medicines at prices lower than those set by local drug manufacturers. The Bill also proposes parallel importing: parallel traders buy goods in a country where drugs are fixed at low levels and sell them at a higher price in an importing country.

Zuma's adviser on the Bill, Dr Wilbert Bannenberg of the World Health Organisation, estimates parallel importing could bring in drugs at prices 15 percent cheaper.

Are medicine prices in South Africa too high? If so, why?
Manufacturers claim that ex-factory prices on patented drugs compare reasonably with other countries. The culprits of high prices, according to the Pharmaceutical Manufacturers' Association (PMA), are huge drug theft — as high as 50 percent of stock — from state hospitals, and the mark-ups by wholesalers and pharmacies.

Zuma has said that some drug prices are 4 000 percent higher here than elsewhere. (This was challenged by the PMA, which referred the matter to the Public Protector's office in July. His decision is awaited.)

The PMA has found that prices of medicines bought by the state on tender are much lower than International Drug Aid prices. Using the International Drug Price Indicator as a guide, South African bulk supplies to the state were found to be 30 percent lower.

Why are South African market conditions different from elsewhere?
South Africa is a developing country that has been awarded First World status and so is not entitled to drug aid from the World Health Organisation.

Labour costs are high in return for low productivity and a high cost of capital.

The trade restrictions of the apartheid years led manufacturers to produce medicines here in quantities that are tiny in world terms and are therefore more expensive to produce.

What is the fight over the Medicines Bill about?
At the core of the argument is Clause 15C of the Bill: "The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public and in particular may: (a) notwithstanding anything to the contrary contained in the Patents Act 1978, determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent."

Will Zuma be infringing international patents law?
The Trips agreement says the patent owner has the right "to prevent third parties not having his consent from the acts of making, using, offering for sale, selling or importing" products.

Opponents to the Bill say South Africa would be in violation of international intellectual property rights which give exclusive rights to sell or import the goods to the trademark or patent owner.

If not, how is she circumventing it?
The Department of Trade and Industry, which worked with the Health Department on the Bill, says it does not view the Bill as a contravention of the Trips agreement as it is wide and open to interpretation.

Bannenberg said public interest could be argued, but the PMA countered that this would only apply in emergencies.

What are the implications for other patented products?
Manufacturers say that if an exception is made to the patent law for medicines, other products will also be open to violation of patents.

Is it worth Zuma's pressing ahead with the Bill?
The prize Zuma is after is cheaper medicines. The penalties, warn pharmaceutical companies, could be poorer quality, unsafe or even counterfeit drugs.

Shisana rules out compromise on divisive drugs bill

BD 14/10/97 (96)

Jacob Dlamini

CAPE TOWN — Health director-general Olive Shisana yesterday challenged the pharmaceutical industry and other opponents of draft legislation aimed at lowering drug prices, to take their case case to the World Trade Organisation (WTO).

Shisana said it had become clear that the department and the pharmaceutical industry did not agree on the interpretation of WTO regulations. Registering a complaint with the WTO would allow the international multilateral trade body to adjudicate on the correct interpretation.

The Medicines and Related Substances Control amendment bill would, among other provisions, allow the parallel importation of drugs from cheaper sources; encourage the use of generic medicines; end the bonusing and sampling of medicines to prevent perverse incentives from doctors' judgments and relax rules for the ownership of pharmacies.

The bill would also give the minister power to overturn decisions of the Medicines Control Council — the body responsible for checking the safety and efficacy of drugs.

Shisana said taking the matter to the WTO would settle the dispute and stop the debate from going "backwards and forwards" as had been happening recently

Shisana said the department had studied the WTO's regulations regarding intellectual property rights and was convinced that it had interpreted them correctly.

She was speaking during a clause-by-clause consideration of the bill by Parliament's health committee.

Shisana denied that the bill, which would give the health minister powers to prescribe additional requirements for the labelling of medicines, would violate patents.

Shisana said: "We are not proposing the busting of patents."

She said parallel imports and generic substitutes would still be inspected by the Council to ensure that it was safe and that it complied with all set regulations.

Shisana's strong stance appeared to dash hopes that changes would be made to the draft legislation to take account of mounting vocal opposition from opposition parties, the pharmaceutical industry and US ambassador James Joseph, who said in a letter to the committee on October 4 that the US opposed "parallel imports of patented products anywhere".

Ian Roberts, a special advisor to Health Minister Nkosazana Zuma, told the committee that the debate on the bill had reached a "bizarre level". He said it would not make sense to introduce legislation which would allow substandard medicines to be brought into the country.

Roberts said that, contrary to opposition party concerns, parallel imports did not raise the risk of drug counterfeiting. He said once parallel importation was in place there would be a clear audit trail to ensure that compounds were not counterfeit.

Meanwhile, Inkatha Freedom Party health spokesman Ruth Rabinowitz called for the scrapping of value-added tax on medicines and for the privatisation of drug supplies to the state to prevent theft. Rabinowitz called for greater competition in the chain of pharmaceutical suppliers, saying this would reduce costs and make health care affordable.

Green light for health products in SA

ARGUS CORRESPONDENT (96) ARG 15/10/97

Johannesburg – Health products including homeopathic, Chinese herbal and traditional African remedies are about to come under the wing of an enterprising new safety and quality control system.

The new electronic listing system will be administered by the Medicines Control Council (MCC) and is expected to be finalised by the end of the year.

The introduction should end months of in-fighting and delicate negotiations over appropriate controls in the complementary health industry.

Health products are neither food nor medicines, but until now rules governing quality of items swallowed by humans applied only to those two groups.

The industry has also had to deal with a flood of unregistered health products in the last three years, and faces a three-to-four year delay in obtaining MCC registration.

Consumers currently have few guarantees of safety, and little objective information about health products because the MCC strictly controls the medical claims made about any product.

The new system allows a wide menu of approved claims about the medicinal value of each product to be printed on the labels.

It also monitors manufacturing processes, which determine the stability, purity, strength and shelf life of a product, The system is considered a world leader because of the broad range of disciplines covered – African traditional, Chinese herbal, Western herbal, Ayurvedic, energy substances, aromatherapy, homeopathy and nutritional supplements.

Recommendations on a listing system for five of these – Western herbal products, homeopathic remedies, nutritional supplements, Ayurvedic medications and Chinese herbal products – were accepted last month. They are due to be ratified by the MCC later this month. It is hoped that lists for the outstanding disciplines will be finalised before the end of the year.

Committee approves Zuma's drugs bill

CT 15/10/97 (96)

A PROPOSAL to allow Health Minister Dr Nkosazana Zuma to permit parallel imports of cheaper drugs was formally approved by the National Assembly's health committee yesterday.

The ANC majority on the committee rejected opposition attempts to amend proposals to ban bonusing, including discounts for bulk purchases, and free sampling, by pharmaceutical companies.

The controversial clauses are contained in the Medicines and Related Substances Control Amendment Bill, which Zuma's ministry says is an attempt to ensure cheaper medicines for all South Africans.

The chief executive of the Pharmaceutical Manufacturers' Association, Ms Mirryena Deeb, said the committee's decision on parallel imports represented a "very, very dark day for all South Africans".

"This is a tragedy not only for the pharmaceutical industry but for all investors in South Africa, both present and potential," she said.

The committee had allowed South Africa's integrity, as a serious international trading player and partner, to be placed in question, she said.

The PMA, whose membership includes a number of multinationals, says it represents 80% of the pharmaceutical market share in South Africa.

Opponents of the parallel imports clause, who include the United States government, claim it violates the international Trade Related Intellectual Property agreement.

The National Part, Democratic Party and Inkatha Freedom Party proposed in the committee that the clause be deleted.

Democratic Party health spokesman Mr Mike Ellis said he found it "incredible" that despite the amount of evidence the committee had heard over the past few months, the health department and ministry were determined to proceed with the step.

"The haste with which this incredibly important thing is been pushed through is absolutely scary, and the repercussions could be so great if this thing is handled incorrectly," Ellis said.

'MEDICINE FOR ALL': Nkosazana Zuma

ANC MP Ms Abigail Njobe said the ANC had listened to all representations on the bill and had done the best it could to determine whether the measure was a move in the right direction.

The ANC was looking at the objective of the clause, which was cheaper medicines, and not merely at the interests of the private sector.

"You have simply forgotten about the people of South Africa whose situation we are trying to address," Njobe told opposition MPs.

Late yesterday afternoon ANC members of the committee unexpectedly asked for an adjournment to discuss a DP amendment to a clause which empowered and obliged Zuma to prescribe a code of marketing ethics for pharmaceutical companies.

Ellis has proposed that the minister be allowed to extend existing codes to cover particular branches or sectors of the pharmaceutical industry, and to prescribe only where there is no code.

The committee is expected to finish its deliberations on the bill this afternoon. — Sapa

Approval for Zuma's 'cheap drugs'

Star 15/10/97 (96)

Cape Town – A proposal to allow Health Minister Dr Nkosazana Zuma to override patent rights by permitting parallel imports of cheaper drugs was formally approved by the National Assembly's health committee yesterday.

The ANC majority on the health committee rejected opposition attempts to amend proposals to ban bonusing, including discounts for bulk purchases and free sampling, by pharmaceutical companies.

The controversial clauses are contained in the Medicines and Related Substances Control Amendment Bill.

Zuma's ministry says the bill is an attempt to ensure cheaper medicines for all South Africans.

'A dark day for investors in SA'

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Elaine Clarke – struggle doctor with new mission

From unsung hero to her new influential role on medicine dispensing body

(96) ARG 16/10/97

ROY WIGLEY

Top doc: Elaine Clarke, new head of the Dispensing Family Practitioners' Association

SHARKEY ISAACS
Staff Reporter

The new chairwoman of the Dispensing Family Practitioners' Association, Elaine Clarke, is a Cape Town doctor who has carved a niche for herself as an unsung hero of the struggle years of the 1980s.

As the co-ordinator of the Concerned Doctors' Action Committee, Dr Clarke, 51, was in the team of voluntary doctors treating high school pupils and university students injured in unrest on the Cape Flats.

From the time she got her MB Chb degrees at the University of Cape Town and completed her housemanship at Somerset Hospital, Dr Clarke made medical history.

She was the first coloured doctor to train as an anaesthetist and her training required her to do clinical work in the wards at Groote Schuur and Red Cross Children's hospitals.

"To get the go-ahead for me to start working at the two hospitals, administrative staff had to consult the white porters first to see whether they objected.

"Fortunately, no one did and I qualified as an anaesthetist in 1974."

This, she said, opened the doors for many other doctors in other fields of medicine.

Dr Clarke practised as an anaesthetist for eight years and then worked as an anaesthetist and a doctor, but found this too demanding.

Concerned about the amount of quality time she was spending with her three children, Dr Clarke switched to working full time as a general practitioner in private practice in Walmer Estate.

She adores her children Nadia, Anees and Zubin and says she is first and foremost a caring mother.

But she also believes children should learn as quickly as possible to be independent.

In 1991, the British Council honoured her with a scholarship which allowed her to get her MSc in Public Health in London.

Dr Clarke also forged close associations with the former residents of District Six and helped them fight to get back their land after the Group Areas Act was scrapped.

Her first association with District Six was when she arrived in the area after matriculating in Port Elizabeth in 1960 and lived in the YWCA in her early medical student days.

Recently, her civil rights role in the community was recognised when she and Neville Alexander were appointed facilitators of the District Six Development Forum's land restitution committee.

Speaking of the violence on the Cape Flats and the dangers facing general practitioners after the killing last month of Valhalla Park doctor Mogamat Refai Dharsey, she advised the medical fraternity to be alert and on their guard in their waiting and consulting rooms.

While Dr Clarke was not considering arming herself, she said she believed it was an issue each doctor had to decide.

The best alternative was to seek police protection and even then it remained to be seen whether 24-hour or even part-time protection would be given. The arrival in Cape Town of additional South African National Defence Force members might be a deterrent but was only a temporary arrangement.

Dr Clarke said a long-term solution was necessary with greater police protection for residents and those who provided vital services.

Meanwhile, she urged doctors to foster goodwill in the neighbourhoods in which they worked and the wider community.

Discussing dispensing doctors' battle to continue dispensing medicines, Dr Clarke said general practitioners were busier than ever and seeing many more patients.

"Contrary to Minister of Health Nkosazana Zuma's belief, township doctors are the vanguard health teams treating the poor.

"Many doctors do not turn away seriously sick patients simply because they do not have the money for treatment."

Some patients saved up to pay for private doctors because the service provided at hospitals was so poor.

She believed that with the continuing influx of people from Transkei and Ciskei, money allocated to rural areas was being misdirected.

Dispensing doctors were the backbone of medicine in Switzerland and other countries.

"Why must we instead tread the same route as other countries in Africa which have already been unsuccessful in providing adequate primary health services for their people?"

The public should be canvassed, through a referendum, whether they wanted doctors to continue dispensing.

"If we are living in a democratic society as they claim, they must ask the people what they want."

Dr Clarke said the package deal dispensing doctors offered patients was far better and more prompt than that at day hospitals or clinics.

"Our fees are also very reasonable and either within or even below medical scheme tariffs. So what is the objection?"

CAPE ARGUS, THURSDAY, OCTOBER

Warning on fake medicines

(96)

ARGUS CORRESPONDENT

ARG 16/10/97

Pretoria – Pharmaceutical companies have warned that lethal counterfeit medicines could make their way on to the shelves of unscrupulous chemists.

This follows the approval this week – in spite of strong opposition – of the Medicines and Related Substances Control Amendment Bill, giving Health Minister Nkosazana Zuma sole control over which medicines are imported, or if parallel importation of a cheaper product is needed.

Critics' warnings that the bill would offend international investors, and that it breached an international intellectual property rights agreement – known as TRIP – have been downplayed by the health department.

The German, Swiss and American embassies each raised concerns over the possible infringement of patent rights, saying the bill sent a negative message to investors.

A Health department spokesman said national pharmaceutical companies felt their patent rights had been compromised, and they had recourse to the World Trade Organisation (WTO).

One drug company employing some 1 200 people in South Africa said it might consider cutting down on staff or withdrawing products.

Pharmaceutical Manufacturers' Association chief executive Mirryena Deeb said there was an increase in fake drugs in South Africa which, to the man in the street, were nearly impossible to tell apart from real medicines.

With parallel importation there was concern that the importation of fake drugs would increase even more.

The Health spokesman said all parties would have until November 14 to submit proposals for the drawing up of regulations aimed at shutting the importation loopholes.

'Dangerous law bulldozed through'

(96)

Josey Ballenger

BD 16/10/97

THE African National Congress (ANC) had "bulldozed" through "dangerous" legislation which would allow parallel imports of cheaper drugs and legalise generic substitution, despite efforts by opposition parties to amend it, the National Party (NP) said yesterday.

The Medicines and Related Substances Control Amendment Bill, approved by Parliament's health portfolio committee on Tuesday night, was likely to increase the price of medicines "instead of achieving the goal of decreasing it" and did not provide a clear separation between the procurers and controllers of medicine (government), said Kobus Gous, NP chief spokesman on health.

Sapa reports health director-general Olive Shisana said the bill, and two others approved last week which aim to reform the health industry, represented a "big success" for her department.

US drugs body threatens court action

BD.171 (96)

Josey Ballenger

THE US pharmaceutical industry said yesterday it would take legal action against the SA government if legislation allowing the importation of patented medical products was passed by Parliament next week.

The Pharmaceutical Research and Manufacturers of America said it was "working with the US government to bring a case before the World Trade Organisation" on the grounds that clauses in the Medicines and Related Substances Control Amendment Bill violated the international agreement on trade-related aspects of intellectual property. Assistant vice-president Thomas Bombelles said the US organisation was also exploring petitioning the US government to take trade action against SA.

Pharmaceutical Manufacturers' Association of SA (PMA) CE Mirryena Deeb said the association was looking at "a number of options" as the legislation seemed to infringe on administrative, patent and competition laws.

Local and international pharmaceutical companies operating in SA have objected to the legislation — which was passed by the parliamentary health portfolio committee on Wednesday and is due to be tabled in Parliament on Tuesday — because it will grant the health minister the right to import equivalent patented products priced differently overseas.

Legal experts say so-called "parallel importation" without the consent of the patent holder is an explicit infringement of the Patents Act.

Tony Hooper, a partner specialising in pharmaceutical issues at law firm Spoor & Fisher, said a patent holder could sue the health ministry for violating the Patents Act, but only if an alleged violation had occurred. Alternatively, a company or the industry as a whole could pursue a case in the Constitutional Court on the grounds that the legislation violated the constitution "in that it gives powers to the minister to override ... the Patents Act".

Section 15 (c) of the Bill says the minister "may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, notwithstanding anything to the contrary in the Patents Act".

"The bill does not put any boundaries on those powers," Hooper said.

Bombelles and Deeb noted the US association could not sue in SA, but that action by the PMA would include the local operations of international companies, which comprised the bulk of its 43 members.

HEALTH POLICY

Cheaper medicine at a price

(96) FM 17/10/97

Minister Zuma and government prepared to take their chances over world trade law on intellectual property rights

The governments of the US, Switzerland, and France have warned the SA government not to adopt Health Minister Nkosazana Zuma's proposed drug reforms. Along with other governments in the European Union (EU), they fear the legislation would infringe upon universally accepted principles of patent protection.

But Zuma is standing firm on one of the most contentious pieces of draft legislation to reach parliament this year, and both the departments of Health and Trade & Industry say they are prepared to fight it out at the World Trade Organisation (WTO).

This will mean fighting fires on all flanks.

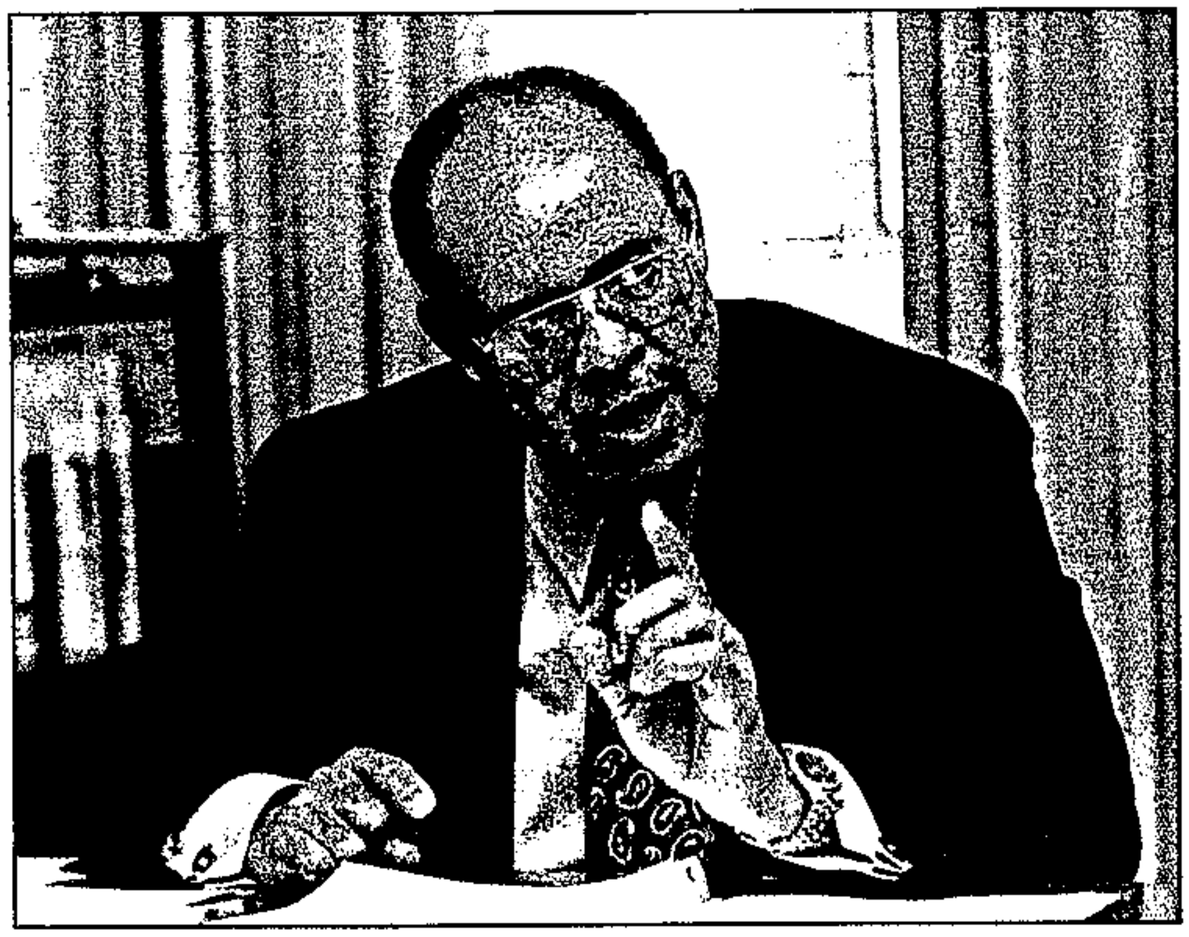
Meanwhile, the Medical Association of SA (Masa) has declared a labour dispute over Zuma's plans to introduce community service for interns in January 1998. And the National Interns' Alliance plans to mount legal action in the Labour and Constitutional courts if parliament gives her the go ahead on October 23.

The Pharmaceutical Manufacturers' Association (PMA) says it will have to consider going to the Constitutional Court to safeguard the R10bn industry's intellectual property rights if the Medicine & Related Substances Control Amendment Bill is passed as is on October 21. Parliament's health portfolio committee is giving its final consideration to the Bill this week.

The US government has maintained a continuous presence at the committee hearings. In a letter to the committee released this week, US Ambassador James Joseph expresses his government's concern over the Bill.

He urges the committee to delete or amend Section 15C(a), which gives the Health Minister the authority to deny patent rights to medicine patent holders — if she thinks this will lower medicine costs.

"The US government is gravely concerned over the public policy implications of a law which would infringe on the intellectual property rights of a patent holder, for even the best of reasons, especially if the power to undertake such action is vested in a single individual," says Joseph. "The governments of France, Switzerland and the EU have expressed similar concerns to your governmen." He also warns that the section sends a negative signal to the high technology investment community.



US Ambassador James Joseph . . . concern over the Bill

US multinational drug company Merck informed the committee last week that it had put its R50m investment in SA on hold and would review all future investments in SA if the Bill was passed.

Joseph also asks the committee to carefully consider the implications of provisions that allow the parallel importation of medicine. (This is when a third party is allowed to import patented medicine into SA from any country where the local economic conditions enable it to be manufactured at lower cost.)

Problems may arise for SA as a signatory to the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (Trips) which gives a patent holder the exclusive right to stop third parties from making, using, offering for sale, selling or importing his products.

The Department of Trade & Industry (DTI) has assured Zuma that the Bill does not violate SA's obligations under the Trips Agreement. DTI acting registrar of patents and trademarks, Craig Burton-Durham, says: "SA is committed to its obligations under the Trips Agreement. We take the view that Trips is open to legal interpretations that have to be tested. Therefore (Minister of Trade & Industry) Alec Erwin has supported the Bill."

However, Burton-Durham refuses to disclose the source of the DTI's legal advice or explain on what grounds the DTI has formed its opinion. Health DG Olive Shisana has challenged the Bill's opponents to take their case to the WTO.

Ranged against the DTI is a barrage of heavyweight legal opinion in the form of senior US patent lawyer Charles Caruso, SA patent law authority Tim Burrell of the SA Institute of Intellectual Property Law, and the International Trademark Association.

The debate over Trips violations has obscured an even greater threat posed by the Bill — the centralisation of power in the hands of the Health Minister.

If the Bill is passed with only minor modifications — and the conduct of ANC members of the health committee suggests that it will be — then Zuma will have sweeping powers over the pricing, sale, safety and registration of medicine in SA.

DP health spokesman Mike Ellis calls for the separation of these powers and urges that final authority over medicine safety and registration continue to reside with an autonomous Medicines Control Council (MCC)."

The Bill contains an overriding clause which allows Zuma to reverse the MCC's decisions if she deems it to be in the public interest." This gives the Minister powers to act virtually autonomously and undo all that has gone before," says MCC chairman Prof Peter Folb.

During committee deliberations ANC members supported the Health Department's view that it was appropriate that the Minister be endowed with the ultimate authority.

Claire Bisseker

US companies to take legal action on new SA medicines law

Star 17/10/97 (96)

The American pharmaceutical industry is to take legal action on its patent rights via the US government if Parliament passes new legislation on medicines next week.

The Medicines and Related Substances Control Amendment Bill is due to be tabled in Parliament on Tuesday.

Thomas Bombelles, assistant vice president of the Pharmaceutical Research and Manufacturers of America (Pharma) said the bill violated the rights of the patent holder to exclusively import and sell its products, violating international trade agreements.

The US government would have to bring the case before the World Trade Organisation on behalf of the industry.

Pharma was analysing its options and working with the government to bring a case before the WTO and also to apply bilateral pressure on the South African Government if the bill passes. – Staff Reporter

Zuma lashed over her 'ill' bills

Medical, legal and international trade drawbacks

ARG 18/10/97 (96)

OWN CORRESPONDENT

Pretoria – Critics have lashed out at the totalitarian powers given to Health Minister Nkosazana Zuma to control the future of health care, charging that three proposed new bills have far-reaching medical, legal and international drawbacks.

The chairman of the Medical Association of South Africa's health policy committee, Ivan McCusker, said that it was an ill-judged, ill-considered decision to allow Dr Zuma to import medicines which might not have been tested, by bypassing the scientific expertise of the Medicines Control Council.

The Pharmaceutical Manufacturers' Association (PMA) says it is going to take Dr Zuma to court over her power to allow parallel imports of drugs.

This follows an ANC majority vote in the health committee of the National Assembly this week, allowing parallel imports of cheaper medicines.

Court battles are already looming, brought by the South African Doctors and Medical Association and the National Intern Alliance, to fight Dr Zuma's decisions to introduce compulsory community service for young doctors.

While the Health Department and Department of Trade and Industry claim that parallel importation does not contravene the so-called TRIPs international agreement, pharmaceutical manufacturers said it could stifle investment, forcing companies to shut down or cut staff.

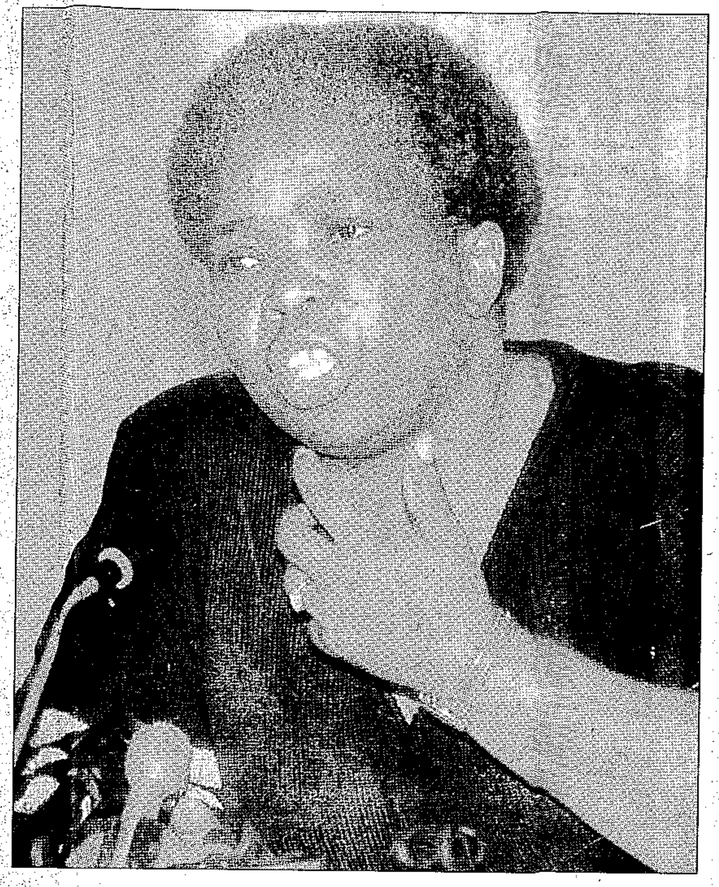
Democratic Party health spokesman Mike Ellis said: "She has been given effective power over the procurement of medicines, the pricing of medicines and the regulation of medicines."

Mirryena Deeb, chief executive of the Pharmaceutical Manufacturers' Association, said the matter could be challenged in the Constitutional Court. A legal team was preparing the case for the association, which represents 43 multinational companies and 80% of South Africa's market.

Dr Zuma has said her first priority is affordable medicines and that legislation will achieve savings of up to 10%. This is questioned by Mr Ellis who says between 30% and 50% of medicines supplied to State medical facilities are stolen and that far greater savings will be achieved by curbing theft.

The NP's Kobus Gous warned that South Africa could be put on a blacklist known as Article 301, which could curb special privileges or even result in sanctions, if the bill was passed by the National Assembly and the National Council of Provinces.

Ms Deeb questioned the neccessity of the bill as any Minister of State who felt a patent right was being abused had recourse to the Patents Act. This would also apply if the local manufacturer could not meet demand or if prices were too high.



Target: Dr Zuma 'fixes on herself a right which exceeds her scientific competence'

US industry to fight proposed SA medicine law at world body

OWN CORRESPONDENT

Johannesburg – The American pharmaceutical industry will take legal action on its patent rights via the US government.

This will happen if Parliament passes the new legislation on medicines next week.

The Medicines and Related Substances Control Amendment Bill was passed by the parliamentary portfolio committee on health this week and is due to be tabled in Parliament on Tuesday.

Thomas Bombelles, assistant vice-president of the Pharmaceutical Research and Manufacturers of America (Pharma), said clauses of the bill violated the rights of the patent holder to exclusively import and sell its products, and so violated international agreements on trade.

The US government would have to bring the case before the World Trade Organisation (WTO) on behalf of the industry, Mr Bombelles said.

Pharma was analysing its options and working with the US government to bring a case before the WTO and also to apply bilateral pressure on the South African Government.

Mr Bombelles said SA was being used as a world guinea pig to push through "anti pharmaceutical industry" policies.

Erwin defends drugs law, suggests WTO intervention

(96)

Jacob Dlamini

BD 22/10/97

CAPE TOWN — Trade and Industry Minister Alec Erwin defended controversial new drug laws last night and said government had taken a policy decision to stop drug companies from using their patents to prevent affordable health care.

In an unexpected intervention in the debate on the Medicines and Related Substances Control Bill, Erwin said he had been in close contact with his US colleagues, and if the matter could not be resolved it should be referred to the World Trade Organisation (WTO).

Erwin said SA and the US differed on the interpretation of a WTO agreement on trade-related aspects of intellectual property that was intended to establish uniformity with regard to property rights.

He said SA was seeking to introduce affordable health care while the US sought to ensure the protection of the long-standing policies of its pharmaceutical industry.

Erwin pointed out that parallel importation was specific to drugs manufactured by the same company but available cheaper elsewhere.

He accepted, however, that there could be an argument that the new legislation was discriminatory.

The African National Congress (ANC) later used its majority to approve the bill's second reading.

To become law, the bill needs the support of the National Council of Provinces and the signature of President Nelson Mandela.

The debate followed a day of drama during which a National Party (NP) motion calling for the bill's withdrawal was voted down by the ANC. NP spokesman Cornelius Botha had argued that parallel importation and generic substitution would violate pharmaceutical companies' intellectual property rights and WTO regulations.

ANC spokesman Abe Nkomo accused the pharmaceutical industry of spreading disinformation about government plans to reform legislation governing medicine control.

Josey Ballenger reports that Pharmaceutical Manufacturing Association of SA CE Mirryena Deeb said section 15 (c) of the bill would put SA "back internationally in an investment sense".

It would "do nothing to bring about cheaper medicine. The state already has access to the cheapest available drugs, and it is losing 50% to theft". She said the distribution chain, not pharmaceutical companies, was what needed reform.

Ivan Kodze, executive director of the Pharmaceutical Society of SA said he did not expect parallel importation to be common practice.

"Dr Zuma has said if the prices of branded products in other countries compare favourably with local prices, there won't be a need (to parallel import) ... it's a threat for industry to bring their prices down."

Fourth attempt to find gambling board members

Janet Parker

BD 22/10/97

THE executive council of the Free State is hoping it will be fourth time lucky in finding nine suitable members for the Free State Gambling and Racing Board.

Free State finance and economic affairs deputy director-general Humphrey Kgomongwe said yesterday the council had, for the fourth and "hopefully last" time, reopened nominations for appointments.

The delay has caused the Free State to lag behind the other provinces in the formation of a regulatory environment for gaming.

The council said in newspaper advertisements "... previous failed nominations were as a result of failure of most of the candidates to fulfil specific criteria".

In a bid to ensure that no further unsuitable candidates were nominated, the council set out an exhaustive list of criteria which would deem a candidate eligible.

Kgomongwe said the council hoped to have the Free State Gambling and Racing Board in place by December, and functional by January. The board would have to "double its efforts and move with terrific speed", he said.

Gauteng pension payouts 'improved'

THERE was a marked improvement in the disbursement of old age and disability pensions in Gauteng, but a great deal more should be done to ensure a more efficient and secure delivery system, the Black Sash said yesterday.

The Black Sash was commissioned by the legislature's standing committee on social welfare to identify problem areas and evaluate the effectiveness of the new pension payout system.

Sash spokesman Sue Sparks said the welfare department's decision to outsource cash payments to a local firm, Cash Paymaster Services, at a cost of more than R1,3m, seemed to be working well.

"Security under them has improved immensely and guards are deployed ... overall things are better. We are excited and optimistic about the future ... now welfare officials can concentrate on solving queries and, hopefully, refine their application process," Sparks said

She said at most payout points the team visited in townships and rural areas, amenities, security and service had improved significantly.

The team also recommended decentralisation of the department's offices to ensure a more speedy delivery system.

Those regions which had decentralised were offering a better service, the team said. — Sapa.

BD 22/10/97

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committee had reaffirmed anisation's position on the enalty as being that it was

'White survival depends on reconciliation'

BD 22/10/97

CAPE TOWN — The survival of whites in SA depended on their joining the process of healing and reconciliation, ANC has accused the media of having had done nothing to contribute to reconciliation but had spent their time bemoaning the passing of the old dispen-

Zuma issues challenge to drug industry

(96)

CT 22/10/97

IF South African medicines were not more expensive than those in other countries, there would be no need for parallel imports, Health Minister Dr Nkosazana Zuma said yesterday.

She was introducing debate in the National Assembly on the Medicines and Related Substances Control Amendment Bill, which will allow her to override patent rights in allowing imports of cheap drugs.

She said the measure would permit parallel imports of a product already registered in South Africa, from a factory operated overseas by the same manufacturer.

If the local pharmaceutical industry's claims on pricing were correct, there would never be a need to use this power. She also asked why, if prices were lower than elsewhere, the industry was opposing the bill.

"The ball is in their court," she said, adding that the clause did not violate any international agreements.

But NP trade and industry spokesperson Mr David Graaff said yesterday that Zuma's bill went against South Africa's commitments in international trade.

It would also affect the country's position as a "bona fide member of the international community", Graaf said.

Freedom Front health spokesperson Mr Pieter Grobbelaar said that while Zuma's aim of providing cheaper medicine was praiseworthy, the message the bill was sending out was not one of creating confidence in South Africa. — Sapa

Drugs firms lashed as controversial medicines bill is passed

By Jovial Rantao
Political Correspondent

Cape Town – As Parliament yesterday passed legislation enabling the Government to import cheaper medicines from overseas, senior ANC MP and chairman of Parliament's health committee, Dr Abe Nkomo, launched a blistering attack on international pharmaceutical companies threatening to withdraw from South Africa if the bill became law.

Major pharmaceutical investors, mostly from the US, had threatened to take the Government to court and to disinvest from South Africa if the Medicines and Related Substances Amendment Bill got the go-ahead.

The legislation was approved yesterday with 201 ANC votes against 71 from the opposition, which included the National Party, the Democratic Party and the Inkatha Freedom Party. Earlier during the proceedings, an NP motion to have the bill withdrawn was defeated by an ANC majority.

Speaking during the second reading of the bill, Dr Nkomo defended Health Minister Nkosazana Zuma and attacked international pharmaceutical companies which he said had deliberately spread misinformation about the Government's plans to reform medicine control legislation.

Nkomo said Zuma's assurances that parallel importation would occur only if the local pharmaceutical industry failed to provide lower prices for medicines was a direct challenge to the pharmaceutical industry to bring down its prices voluntarily.

"What we're doing is not new. Norway, Japan, Iceland and the European Union countries already allow the parallel importation of medicines. Yet it is only our minister of health who is lambasted by the giant pharmaceutical companies. If she was wrong, why are they silent on the other countries? Is it because they see the developing world as a soft touch?" Nkomo charged.

He rejected allegations that the legislation would sidestep companies' patent rights by importing cheaper alternatives to primary branded medicines.

Introducing the debate on the most controversial of her three bills, Zuma said steps would be taken to ensure that quality medicines would be imported.

Star 22/10/97 (96)

Govt denies Zuma held back report on health bill

BD 24/10/97 (96)

Jacob Dlamini

CAPE TOWN — The trade and industry department yesterday denied National Party (NP) claims that Health Minister Nkosazana Zuma had withheld a vital departmental report on one of the controversial health bills from Parliament's health committee.

NP spokesman Kobus Gous alleged that Zuma had failed to release a report issued by the trade and industry department's advisory committee on patents, trademarks, copyright and designs in June this year.

Gous said the committee had advised Zuma against putting the bill through Parliament because it violated SA's international obligations to the World Trade Organisation (WTO).

The Medicines and Related Substances Control Amendment Bill was approved by Parliament earlier this week. It will enable government to import parallel drugs from cheaper sources and encourage generic medicines.

Gous said the NP would ask President Nelson Mandela not to sign the bill into law until his claims had been probed.

But the NP claim has been rejected by Greig Burtham-Durham, the department's acting registrar for patents, copyright, trademarks and designs.

Burtham-Durham said no report had been issued and that the advisory committee, chaired by a senior judge, had not met formally to consider the draft bill.

Zuma's spokesman Vincent Hlongwane accused the NP of making mischief.

Hlongwane said the department had been consulted and that it, in fact, had drafted clause 15C of the bill, which allowed for parallel importation.

Hlongwane said the department had been unhappy with the health department's formulation of the clause in the first draft and had carefully rewritten it to ensure that it complied with WTO regulations. He denied a report had been issued.

The third of Zuma's health bills, the Pharmacy Amendment Bill was read a second time yesterday and supported by all parties except the Democratic Party (DP). It is designed to open ownership of pharmacies to lay people.

A DP spokesman said the pharmacy profession would become subject to the political and personal bias of the health minister once the bill became law.

MEDICINES CONTROL BILL

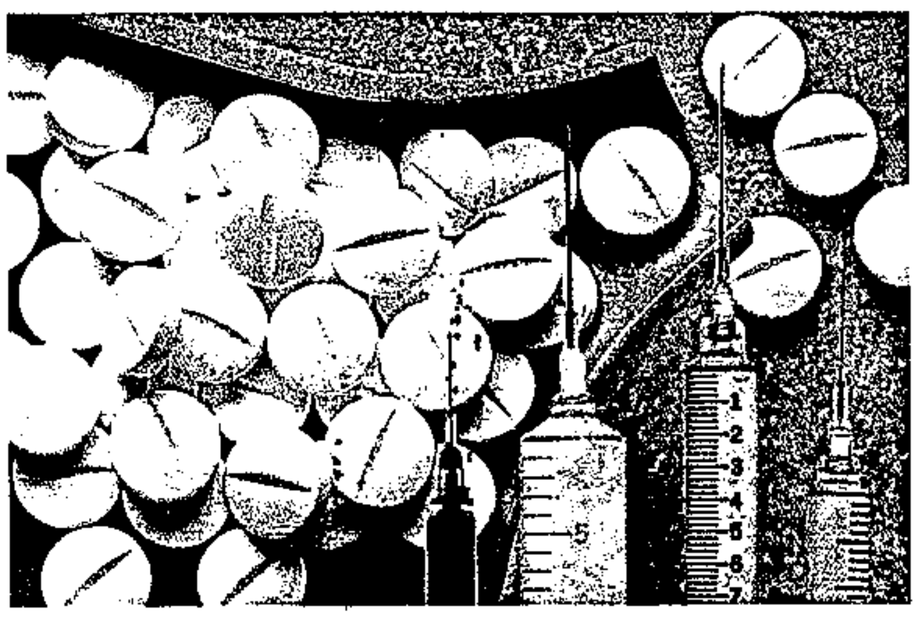
Beware of counterfeit medicines, Kenya warns SA

FM 24/10/97 (96) (185)

Kenya has banned as unsafe a key element of the controversial medicines Bill which the ANC has pushed through the Assembly

The National Assembly has passed the fiercely contested Medicines & Related Substances Control Amendment Bill which aims to make medicine cheaper, but dire warnings from Kenya indicate where SA may be headed.

Kenya has outlawed a key strategy of the Bill — parallel importation — having found evidence of substandard and counterfeit drugs in the country.



This warning is contained in a letter to Medicines Control Council (MCC) chairman Prof Peter Folb from the director of the Kenyan National Quality Control Laboratory, Dr Elizabeth Ominde-Ogaja.

The letter, dated October 14, aims to alert Folb to Kenya's failed experiment with parallel importation and the consequences of allowing political interference in the scientific decisions of the drug regulatory authority — the two most contentious aspects of Health Minister Nkosazana Zuma's Bill.

The letter was leaked to the *FM* by a third party and is used with Folb's knowledge but not his permission.

Parallel importation occurs when a third party is allowed to import into a country a patented drug from another country where it is cheaper, bypassing the manufacturer's official distribution network.

Though parallel importation can mean cheaper drugs for consumers, Folb repeatedly warned the health portfolio committee that unless the Bill stipulated that these drugs be subject to the same safety and registration procedures as local medicine, it would open the door for counterfeits.

Despite his evidence and the opposition of the pharmaceutical industry and the US and European Union, who regard it as a violation of universally accepted principles of patent protection, the committee passed the relevant section unamended.

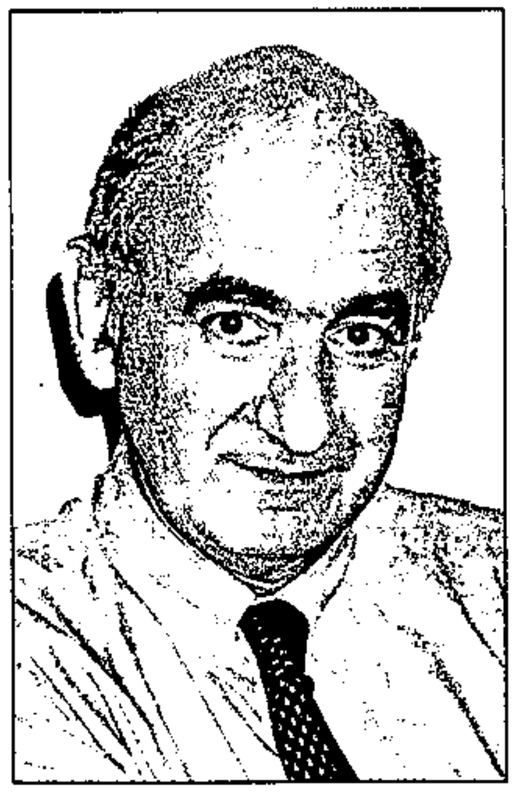
The letter says the Kenyan authorities' biggest problems were ascertaining whether parallel imports had been produced in accordance with good manufacturing practice, and their inability to recall unsafe products.

Other problems included the persistent threat of patent infringement challenges and consumer confusion over multiple presentations of the same product.

Kenya has uncovered "alarming evidence" of substandard and counterfeit products and the Pharmacy & Poisons Board has outlawed parallel imports, mainly for safety reasons.

Parallel importation is also illegal in the US, both as an infringement of patent rights and because the US Food & Drug Administration feels it cannot adequately monitor the quality of medicine imported.

Quizzed on this topic during committee hearings, Zuma's special adviser Dr Ian Roberts said parallel importation is used successfully in the UK. In SA, importers will be required to present various clearance certificates and a clear audit trail will, in theory, enable the MCC to trace parallel imports back to their source to ensure safety standards are maintained.



Prof Peter Folb

Zuma says the Bill will achieve savings of up to 10%. But DP MP Mike Ellis says that not only has the Health Department failed to provide any documentation to prove any of its claims, but far greater savings can be achieved by stopping theft of 30%-50% of the medicines at State facilities.

One of the most contentious aspects of the Bill is that it allows Zuma to replace the Registrar of Medicines and to veto and reverse the decisions of the MCC, one of the top 10 drug regulatory authorities in the world.

In Kenya the exact opposite is happening: the Health Ministry is making the Pharmacy & Poisons Board financially and politically independent. The board's previous registrar was a Ministry official, "resulting in the hindrance of the board's objectivity with decisions often being made on political rather than public health grounds," says Ominde-Ogaja.

It is a warning that SA ignores at its peril. The letter's main points were raised repeatedly in the committee by numerous organisations, not least by Folb himself. Given the lack of counter-evidence from the department, hard questions must be asked about the committee's handling of the Bill.

Though it allowed sufficient time for public hearings, ANC members stand accused of putting blind faith in Zuma ahead of the evidence before them.

"The overall impression created by the ANC and the department was that they were not prepared to entertain or apply their minds to any of the many amendments proposed by the NP or other opposition parties," says NP health spokesman Kobus Gous.

"They are virtually acting in a vacuum of what their ideals and ambitions are," says Malcolm Barlow, international health consultant to SmithKline Beecham.

Barlow visited SA last week to discuss strategy with the pharmaceutical industry, which is girding for a long and costly legal battle over the Bill, first in SA courts and, failing that, at the World Trade Organisation.

SmithKline Beecham shares the approach of US drug multinational Merck, which has said it will evaluate all future investments in SA against the Bill.

"The real tragedy," says Barlow, "is that we look at SA as the regional hub for exporting our products into southern and ultimately sub-Saharan Africa. That won't happen if we cannot find a free market situation here."

The Bill was passed by the ANC majority in the National Assembly on Tuesday. It now goes to the National Council of Provinces for further debate.

Claire Bisseker

Zuma's medicine for the nation

(96)

Minister speaks of need for 'national consensus' on the question of quality care

Star 24/10/97

By Jovial Rantao
Cape Town

Taking a leaf out of Deputy President Thabo Mbeki's book, Health Minister Dr Nkosazana Zuma has called for "a national consensus" on the plight of the poor, the sick and the vulnerable.

Her call echoes Mbeki's appeal earlier this year for national consensus on nation-building.

Zuma addressed the National Assembly in Cape Town yesterday, where the Pharmacy Amendment Bill, the last of her three controversial health bills, was passed by the assembly amid objections from the Democratic Party, Pan Africanist Congress and the African Christian Democratic Party

The National Party and the Inkatha Freedom Party voted in favour of the measure.

She said quality health care was a matter on which there should be a national consensus, irrespective of party affiliation.

"Listening to the debate on the other two bills, I could not help but feel sad about the fact that the passionate speeches of those who opposed the bills had nothing to do with the plight of South Africans who need access to health care.

Last of her three bills is passed

"The thread that runs through was defence of the fittest, the privileged, the wealthy and the powerful. No compassion was expressed for the poor, the sick and the vulnerable.

Sad as this may be, it indicates that indeed an ongoing debate is necessary to reach a national consensus, particularly on the type of society we're creating," Zuma said.

She said the pharmacy bill was about transformation, both in the manner in which pharmaceutical services were rendered and the statutory council that would be responsible for ensuring that pharmaceutical services were rendered in the interests of the public and under strict and ethical conditions.

Among others, the Pharmacy Amendment Bill provides for the ownership of pharmacies by non-pharmacists.

The Department of Health has argued that many communities in rural areas and black townships do not have access to full pharmaceutical services.

The legislation seeks to make it possible for non-governmental organisations to set up pharmacies in the underserved areas.

The only condition required by the bill is that the pharmacies must be operated under full supervision and management of a qualified and registered pharmacist.

This legislation has been vehemently opposed by pharmacists who fear they would be pushed out of the market by big supermarket chains.

Democratic Party health spokesman Mike Ellis said his party's objection was not against the objectives of the bill, but against the powers it granted to the minister.

Anyone can own pharmacy

■ The National Party is to ask President Nelson Mandela to delay signing the Medicines and Related Substances Control Amendment Bill into law because a crucial memorandum from a government committee on patent rights was withheld from the health portfolio committee.

Medicines easier to swallow in 1998

(96)

They WILL cost less in spite of controversy and threats of legal action

ARG 27/10/97

INSIDE STORY

In spite of all the controversy around the new health bills, medicines will cost less next year, reports **JENNY VIALL**, Health Reporter

The Medicines and Related Substances Control Bill has been passed by the National Assembly – and amid the controversy and threats of legal action against the Government, one thing is certain: medicines will cost you less from next year.

That's the opinion of Aslam Dasso, of the Representative Association of Medical Schemes (RAMS).

Three provisions of the legislation make this possible. The first is the removal of the profit incentive from the sale of medicines, the second is the setting of a single exit price for manufacturers and the third is forcing pharmacists to give people the option of buying a generic medicine.

The new law says that anybody who dispenses medicines may not profit from the sale of that medicine, but may charge a professional fee to be determined by a pricing committee. This committee will take anything from six months to a year to function fully and RAMS has negotiated a fee for the interim period.

This is how it will work and how it will save you money:

When you buy prescription medicine now, you pay the cost of the medicine to the pharmacist plus a 50% mark-up. It makes economic sense for the pharmacist or doctor to sell you the most expensive medicines because these make the most profit.

That contributes to the private sector's annual very high R7-billion medicine bill. This means higher medical aid premiums, which are already increasing at almost double the inflation rate.

That system will no longer operate. The new bill says there will be no profit on medicines, the mark-up is taken away and this is replaced by a professional fee.

From January pharmacists and doctors who dispense medicines will be paid the dispensing fee according to a system worked out by RAMS.

A single dispensing fee is not feasible, says Dr Dasso, because cheaper medicines then become too pricey.

Mixed medical aid schemes (catering for both the top and lower end of the market) would come out "budget neutral", but those at the lower end of the market would end up paying more.

A medicine now priced at R10, with a 50% mark-up, costs you R15. Under the new system, if you add a R20 dispensing fee, the same medicine will cost R30, which is clearly not a cost reduction.

At present for expensive drugs, for example a R200 item, a 50% mark-up makes it R300. But with only the proposed professional fee of R20 added, the medicine would cost R220, clearly a saving.

"So we said here is the dilemma. The pharmacy council could not countenance a differential fee because dispensing is a service and is not linked to price of medicines.

"The Government has its own battles and the pharmacists want the best deal they can get," says Dr Dasso.

The compromise is an innovative solution which takes into account everybody's concerns.

All medicines costing up to R30 will still have a 50% mark-up.

Drugs costing more than R80 will attract a flat professional fee of R24 an item up to three items (the rest at cost price).

Those medicines from R30 to R80 will have a sliding scale fee of R15 to R24.

Medical schemes will have the option of adopting the pricing scheme, but it is likely that most of them will do so.

"Medicines cost the private sector R7-billion a year. If we can save even 1%, it is worth it," Dr Dasso says.

The second change is the pricing structure of drugs.

"The core issue was finding out what manufacturers were selling medicines for, the true cost price. It was an exercise of great frustration.

"Eventually, we got hold of a list and we will meet manufacturers soon to discuss cost prices," says Dr Dasso.

Further savings will be effected by the provision in the bill that pharmacists tell people about generics – drugs which have exactly the same active ingredients, but are much cheaper.

"Medical information has been kept secret for too long: knowledge is power," says Dr Dasso.

"If doctors write N/S (no substitution), the pharmacist may not substitute a generic. So everyone is catered for.

"Generics in this country are safe and they work. And they cost a whole lot less," he says.

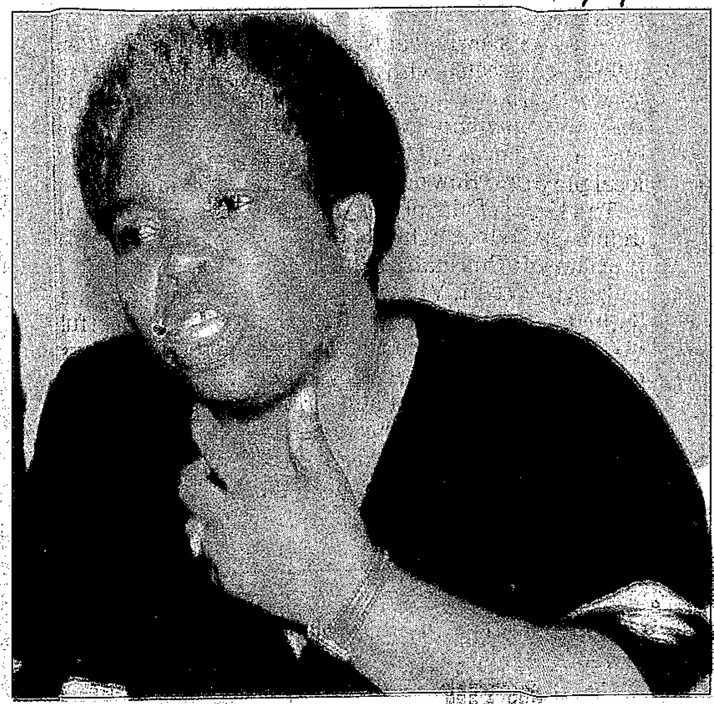
Why do we need to reduce health expenditure in the private sector and why has the private sector reacted so strongly against this bill?

"Projected services to medical scheme members in 1997 will cost R20-billion for just under seven million people, 17% of the population. The Department of Health's budget is R20-billion, for 83% of population," says Dr Dasso.

"This stark disparity underlines how screwed up our health care system is.

"High drug prices make the private health care system unprofitable and overheated.

"And it is dumping people on to the state."



Cheaper care? Health Minister Nkosazana Zuma, who wants to lower medicine costs

Fears over move to allow psychologists to prescribe

CT 27/10/97 (96)

LISA TEMPLETON

PSYCHOLOGISTS may soon be able to prescribe medicines, but psychiatrists fear their lack of medical training may endanger their patients' health and possibly their lives.

To date the prescription and administration of medicines has been the strict domain of doctors and dentists, who are medically trained, but the Medicines and Related Substances Control Act would open the way for other health workers to prescribe.

The controversial act, which has been approved in principal and is expected to be passed later this month, is a move to broaden the base of prescribing health professionals to make them more accessible to people in rural or disadvantaged areas.

Other professionals to benefit from the act include opticians, dieticians and physiotherapists.

The possibility that psychologists will be able to prescribe medicines has outraged their medically trained counterparts, the psychiatrists, who fear the psychologists' lack of medical training could put their patients at serious risk.

"For example, if a patient with serious heart problems is prescribed a common anti-depressant, there is a 60% chance that the patient will die in two weeks," one psychiatrist said.

Dr Saths Cooper, president of the Psychological Society of South Africa (Psyssa) said the following conditions were fundamental to the right of psychologists to prescribe and administer medicines:

- They would have to undergo training in psychological pharmacology.
- They would be limited to a list of medicines approved by the Professional Board of Psychology.

"In practice a lot of health professionals like nurses have been prescribing, but legislation is so archaic — with almost Victorian prudishness — that prescription has remained the preserve of doctors and dentists," Cooper said.

"The effect of this has been high costs because clients had to get medicines prescribed by a doctor or psychiatrist after seeing a psychologist."

> *'Legislation is so archaic that prescription has remained the preserve of doctors and dentists.'*
> *— Saths Cooper*

In practice too, many psychologists have been making recommendations to general practitioners as to what to prescribe for their clients, but this is illegal.

At present, Psyssa and the Professional Board of Psychologists are discussing with universities and training institutions the roles of training and registration of psychologists, and a draft paper is to be debated at universities countrywide.

The issue is also being debated in Britain and America, and the American Psychological Association has offered South Africa its training package and back-up.

"As this is a new area of practice with very serious ramifications for patients there will have to be liability insurance and intensive training for psychologists," Cooper said.

So what do psychologists stand to gain from this?

Professor Graham Lindiger, of the University of Natal in Maritzburg's psychology department, said: "The sub-text is about power and money, but no one is saying that. The implicit message is that prescribing medicine gives one status and financial rewards."

Professor Don Foster, of the department of psychology at UCT, said it would bring fees parity between psychiatrists, who now earn substantially more, and psychologists. How have psychiatrists reacted?

Dr Francois Daubenton, of the department of psychiatry at UCT, said: "The prescription of medication requires an understanding of pharmacology, the anatomy and physiology of the body and the possible interaction between psychiatric medications and those prescribed for other illnesses. In medicine these disciplines take three to four years of training."

Professor Clifford Allwood, president of the Society of Psychiatrists of South Africa, called for pschologists to be made accountable, so they could be censured like doctors.

Warning on 'drug meddling'

(96)

Council nervous about interference in regulation of drugs

Star 27/10/97

By Janine Simon
Medical Correspondent

The Health Ministry and its department risk causing deaths and the total decline of the health system if they abandon their promises and meddle in the drug regulatory process, the Medicines Control Council (MCC) has warned.

The health minister's newfound legal rights over drug regulations were sealed last week when the hotly contested Medicines and Related Substances Control Amendment Bill was passed by the National Assembly.

The bill gives the minister the right to appoint a new council and committee of scientific appeal, and to intervene in setting the regulations for drug registration. She can now also sidestep local manufacturers and "parallel-import" a drug already registered and distributed in South Africa.

Manufacturers said parallel importing represented the wholesale abrogation of their patent rights, and opened the way for counterfeit drugs to flood into the country.

The effect on the authority of the council has been likened to putting an independent judiciary under government control.

The council, one of the World Health Organisation's model drug regulatory authorities and one of only two effective agencies in Africa, has decried the bill as thoroughly unsound.

Now that the law has been changed, the challenge was to ensure that no political interference took place, chairman Professor Peter Folb said.

The council did not expect catastrophe, provided the minister kept her assurances to the portfolio committee on health that all imported medicines, and the facilities in which they were manufactured, would be subject to rigorous council examination.

"If there is interference we can't say what will happen, but the public will know, and it is the duty of the MCC to tell them," Folb said.

In a worst-case scenario, political interference could lead to deaths. The more subtle long-term threat was that the breakdown of the regulatory process for medicines had been at the heart of the breakdown of the pharmaceutical and health systems in some countries surveyed by the World Bank, he said.

Good regulation kept drug prices down because it guaranteed the quality of unknown brands. Without it, better-grade drugs became a scarce, expensive commodity, and the poor suffered, Folb said.

The mixing of drug regulation with political function is opposed by the World Health Organisation.

In a recent letter to the council – released by a third party and not by the MCC or with Folb's permission – the Kenyan National Quality Control Laboratory warned that parallel importing made it difficult to assess whether the drugs were made according to sound manufacturing processes, or to recall them if they were found to be unsafe.

Kenya has now banned the process and is again separating its drug-regulatory body from political appointments.

The MCC considers itself efficient by comparison with other regulatory authorities. It does 70 000 spot checks a year on drugs in the market; has 8 500 interactions a month; and takes an average of 240 days to evaluate a generic drug, although this can be shortened when the use of a drug is in the public interest.

Drug law tonic for SA industry

(96) BD 28/10/97

MULTINATIONAL drug companies may be jumping up and down about the latest health legislation, but local manufacturers are not.

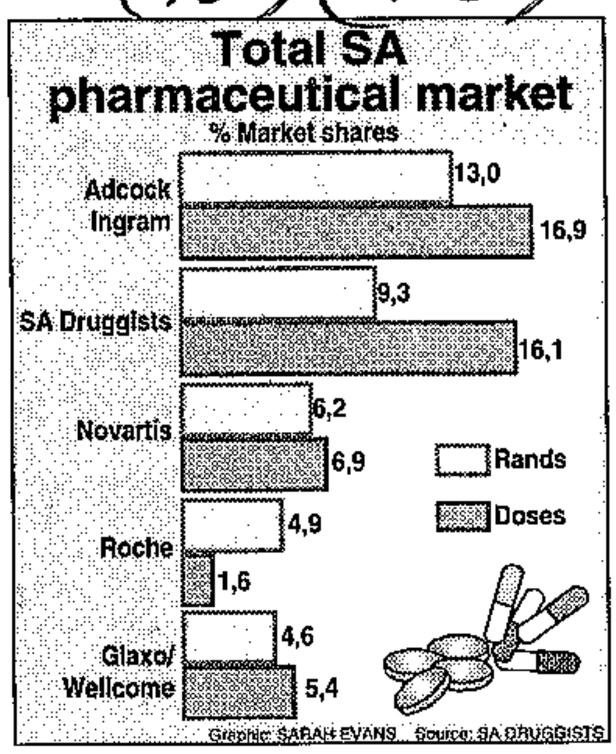
Adcock Ingram and SA Druggists (SAD), both of which reported year-end results last week, are unconcerned about Health Minister Nkosazana Zuma's new legislation, which is intended to cut SA's high medicine costs.

Unlike the multinationals, who rely mainly on the manufacture of so-called "ethical" (original research-based) drugs, the local manufacturers derive much of their revenue from cheaper "generic" medicines and over-the-counter self-medication drugs.

Precisely how the new law will work is unclear as the regulations have still to be promulgated. But Adcock Ingram said it was strategically well placed "with its strong position in the hospital products and over-the-counter markets which are less susceptible to proposed legislation and more adaptable to market changes".

SAD chairman Peter Benningfield said last week the impact of the new legislation would be less for his group than for others in the industry. Ethical drugs were likely to be under threat and SAD could benefit from a swing to generics.

Total market figures are not available, but SAD estimates only 17% of the R2,7bn worth of drugs prescribed annually by SA's private doctors are generics. In the UK, by contrast, 60% of drugs used are generics.



Benningfield said SAD was well placed to take advantage of the new laws, since its average cost per dose was 25c against an industry average of 44c. SAD measures a dose as the smallest unit of medicine — one tablet, capsule or 5ml of liquid. SAD estimates the leading multinationals in SA, Novartis, Roche and Glaxo Wellcome have seen their share of SA's private pharmaceutical market fall over the past year while SAD gained market share both in value and dose units. Adcock Ingram also gained in value but lost slightly in dose units.

Adcock raised headline earnings a share 27% in the year to September, the first full year of operation of the "new" Adcock created by the merger last year with Premier Pharmaceuticals. As the graph shows, it has the leading share of SA's R6,9bn pharmaceutical market, followed by SAD.

Analysts reckon much of Adcock's earnings growth came from rationalisation and synergy benefits flowing from the merger. Some are asking what will drive Adcock's growth 12 to 18 months on, once merger benefits are all through. "It needs a major acquisition — but there is nothing large to buy in SA," says one analyst. The group has cash resources of R645m and is ungeared. It is believed to be out shopping, but the question may be to what extent it can deploy its funds offshore.

SAD is also looking to further offshore expansion to add to its interests in the UK (generics distributor Lagap Pharmaceuticals) and Italy (Pharmatec). Benningfield notes SA's pharmaceutical market represents only about 4% of the world market. "We have to look internationally to ensure our long-term future," he said.

SAD's headline earnings q share rose by a mere 1,3% in the year to August. Its pharmaceutical division, Pharmacare, did well, contributing 81% of the group's operating income. But the managed health care and chemical divisions underperformed.

government. gramme projects.

Medicine bill 'in conflict' with international rights

BD 3/11/97 (96)

Pearl Sebolao

THE SA Institute of Intellectual Property Law has criticised the passing of the Medicines and Related Substances Control Amendment Bill by the National Assembly last week, saying it is in conflict with various articles of the Trade-Related Aspects of International Property Rights (Trips) agreement to which SA is obligated.

Institute president Reinhard le Roux said that although the institute supported Health Minister Nkosazana Zuma's quest for affordable health care, it was concerned that section 15(c) of the bill, which sought to bypass pharmaceutical patent rights to permit parallel importation was wholly in conflict with SA's international obligations.

As a member of the World Trade Organisation (WTO), SA was automatically a signatory to the Trips agreement.

The institute, whose membership consists of more than 200 SA lawyers specialising in patents, trade marks, copyright and related fields, had made presentations to the parliamentary health committee in this regard.

Le Roux said SA would be perceived as a country which did not provide adequate protection for intellectual property rights and by failing to honour its obligations to the WTO, it could be faced with severe international sanctions.

The institute warned that far from making medicines cheaper, many pharmaceutical products would no longer be available in SA as the international drug companies would withdraw their products and investments because of inadequate patent protection.

Parallel importation was not the solution and would open avenues for dangerous counterfeit products, he said.

Le Roux said that the law was unnecessary since the SA Patents Act made provision for Zuma to use an invention for public purposes. It also made provisions for her to obtain a compulsory licence if patent rights were abused.

Gauteng to hold public hearings on controversial drug legislation

(96) BD 4/11/97

Josey Ballenger

SIXTEEN organisations were expected to make submissions to the Gauteng legislature's health committee in public hearings on Thursday on legislation allowing government to import "parallel" drugs, committee coordinator Charity Ndlovu said yesterday.

The Pharmaceutical Manufacturing Association (PMA), which represents many multinational companies and has been one of the most vocal opponents of the Medicines and Related Substances Control Amendment Bill, said its submission would not be substantively different from the one it made to parliament last month.

Public hearings on the medicines bill will also be held in Mpumalanga on Friday as part of provincial government consultations on legislation falling under their jurisdiction. The consultation follows the National Assembly's approval of the bill and precedes its referral to the National Council of Provinces.

The council will vote on this and two other health bills on November 20.

The parties scheduled to make submissions included the National Association of Pharmaceutical Manufactuers, representing mainly generic drug companies; the Pharmaceutical Society of SA; the Medical Association of SA; the SA Chamber of Business; the SA Institute of Intellectual Property Law; and generic and over-the-counter drug group SA Druggists.

The US government and multinational drug companies such as Merck and SmithKline Beecham are among those who claim the bill violates international agreements on intellectual property rights under the World Trade Organisation, and have threatened legal action against the SA health ministry if the bill becomes law.

Local Merck subsidiary Merck, Sharpe & Dohl has already put a R50m manufacturing investment on hold following its re-entry to the country last year.

The US embassy's information officer in Pretoria, Bruce Wharton, said the US government would not comment, as it wished to scrutinise the legislation in its final form.

Zuma fends off warnings about cheap medicine lines

Nicola Jenvey (96) BD 11/11/97

DURBAN — Health Minister Nkosazana Zuma fended off tense warnings yesterday with the private sector and KwaZulu-Natal premier Ben Ngubane, urging her against procuring cheap medicine lines that in the long term would cost SA "dearly".

At the opening of the Smith & Nephew R8m wound-care facility, Smith & Nephew medical director Kelvin Johnson requested the national administration "not to entertain deteriorating standards, to demand that procurement administrators adhere to minimum specifications on tenders, and to be constantly sensitive to the role local manufacturers played in supplying cost-effective treatment".

Johnson said the local market accounted for 80% of capacity and without the state as a major customer and the support from the private health-care sector, the employment provided by the company would be in jeopardy.

"Hopefully health-care leaders share the vision that in our industry there is no compromise on quality."

Ngubane echoed these sentiments, urging Zuma's ministry to acknowledge that without sufficient profits, health-care manufacturers would not continue in business. Production decisions were based on "realistic profit margins". He urged the state to favour those manufacturers that used labour-intensive production methods when awarding state tenders. This meant companies, including Smith & Nephew, would be rewarded with increased economies of scale for providing local employment.

Zuma said the responsibilities of the new government meant "nothing traps us in that (apartheid) past" and the new health policy had to include equity, accessibility and affordability.

"It is essential that all health-care role players play their (part) in assuring SA has affordable health care. The private sector has its role to play and so do individual companies, Smith & Nephew not excluded," she said.

While acknowledging the private industry had to be profitable to survive, Zuma found it unacceptable that SA was "burdened by a higher cost" for medicines and medical products than many countries around the world. She demanded the private industry provide competitive prices in a global marketplace for products that had reached world quality standards.

Zuma denied "taking on the giants", but rather demanded that those previously denied access to health care receive a value-for-money product.

Personnel eat up provincial budgets

Jacob Dlamini BD 11/11/97

CAPE TOWN — Eight of the provinces spend more than 50% of their budget allocations on personnel costs, figures released by Constitutional Affairs Minister Valli Moosa yesterday show.

The Northern Province, which was allocated R10,3bn for the current financial year and is regarded as being one of the two poorest provinces in the country, spends 59,97% of its budget on personnel. Next is Eastern Cape, which spends 55,11% of its R13,7bn budget on the same item.

Of R4,8bn given to Mpumalanga, 54% goes on personnel. In the Free State (R5,5bn) and KwaZulu-Natal, allocated the largest amount of R15,4bn, the figure is 53%. In North West and Western Cape it is 52%. Gauteng spends 50,67% of its R12,9bn budget on personnel. Northern Cape, the biggest province in terms of land but with the smallest population, spends 46,04% of its R1,9bn on personnel.

Zuma offers olive branch to healthcare manufacturers

CT (BR) 11/11/97 (96) CT (BR) 11/11/97

SHIRLEY JONES

Durban — Nkosazana Zuma, the health minister, yesterday offered an olive branch to health care manufacturers at the opening of a Smith & Nephew wound care factory in Pinetown, KwaZulu Natal.

"Industry and the government should work together rather than take on one another," she said.

However, she had to contend with strong criticism.

Kelvin Johnson, a Smith & Nephew director, said the state should not ignore the value of investments such as the one which had resulted in the creation of a wound care facility capable of manufacturing to stringent export standards while serving up quality products to the local market.

"Without the state as a major customer, without the support of the private sector, our company and the jobs we provide are at risk," he said. "Hopefully, our healthcare leaders share our vision that ... there can be no compromise on quality. . . .

"Our request to your administration, Minister Zuma, is not to entertain deteriorating standards, to resist the temptation for procuring cheap lines that in the long term cost our industry dearly ... and to be constantly sensitive to the role local manufacturers can play in the supply of cost effective treatment regimes," said Johnson.

Zuma said she intended to extract the maximum value for each rand spent on providing a healthcare service for those who had been denied this in the past.

She accused industry and the media of distorting her intentions. Once they understood these, it would be possible to identify the roles each could play in providing a cost effective healthcare system accessible to all South Africans, she said.

Zuma said the government had no intention of chasing away major healthcare manufacturers. The sector was worth investing in and the government needed industry as much as industry needed the government.

Without industry, it would be impossible to provide a quality healthcare service. "We're not in the business of providing primitive healthcare," Zuma said. The health department would not compromise on standards.

It had had no increase in real terms since the days of the old government when it was catering for a far smaller portion of the population. Marginal increases had been eroded by inflation, she said.

Although her department wanted cost effective rather than cheap medicine, it needed to look at the entire chain from prescriber to dispenser to manufacturer. Zuma stuck to her guns — both over-servicing and high prices from manufacturers pushed up costs, she said.

Trade dept's change of heart on medicines bill

Star 14/11/97 (96)

The Department of Trade and Industry has played down its criticism of the new medicines bill, saying only the World Trade Organisation (WTO) can determine whether it in fact violates its TRIPS agreement on intellectual property rights.

The bill was endorsed by six of the provinces in the National Council of Provinces yesterday, with the Western Cape opposing and KwaZulu Natal and Free State abstaining.

Prior to the hearing the chairman and vice-chairman of the department's advisory committee told the Free State legislature it was their opinion that Section 15(c) of the Medicines and Related Substances Control Amendment Bill violated international and local patent rights.

But department spokesman Themba Rubushe maintained that the broad consensus of opinion sought worldwide was that the bill did not contravene the agreement. The department remained convinced that the legislation was within the law, and would go ahead unless the (WTO) ruled otherwise. – Medical Reporter

Submissions that health minister withheld information from Parliament

Zuma under more fire over drugs bill

Star 15/11/97 (96)

By PIETER MALAN and SAPA

Health Minister Nkosazana Zuma's integrity has been called into question by opposition parties after it was alleged this week she withheld information from Parliament.

Opposition parties said yesterday Zuma had held back vital information from the National Assembly's Health Committee in her quest to "bulldoze" controversial medicines control legislation through Parliament.

National Party (NP) health spokesman Kobus Gous said his party wanted to know why Zuma had "misled" Parliament, while his Democratic Party (DP) counterpart Mike Ellis said the measure, designed to allow parallel import of cheaper drugs, should be withdrawn.

The attack follows the disclosure of a document this week in which the Government's advisory committee on patents and trademarks said the proposed Medicines and Related Substances Control Amendment Bill would contravene a major international agreement on intellectual property rights which South Africa had signed.

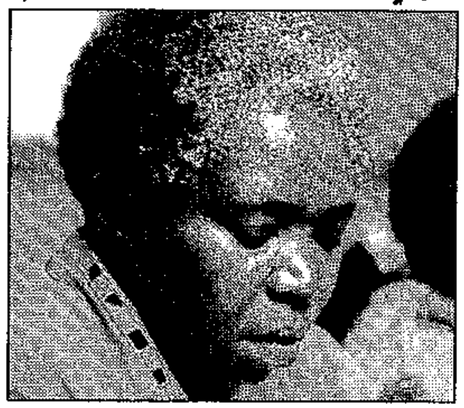
Advisory committee chairman Judge Chris Plewman and vice-chairperson Esme du Plessis said the medicine bill would also violate SA patent law.

Their memorandum – a result of a NP investigation into the matter – was made public this week at a meeting of the National Council of Provinces' (NCOP) social services committee, which debated and approved the legislation.

Plewman and Du Plessis also confirmed their committee had given a similar opinion earlier this year on an earlier version of the bill, since withdrawn, which had been available to Zuma.

Gous said yesterday that the first opinion had, however, not been forwarded to the National Assembly's health committee, and asked what President Nelson Mandela was going to do about the lack of transparency in his government?

Ellis said it was absolutely unacceptable that Zuma could have had the information yet not told the portfolio committee. "I am concerned the minister has deliberately misled the committee and Parliament. It would not be the first time ... This incident calls her integrity into question."



AMBIGUITY: Did Health Minister Nkosazana Zuma mislead Parliament?

Plewman and Du Plessis were approached on November 10 by the legal adviser of the Free State legislature. He asked for their opinions on the bill, then being debated by the province's health committee.

They said they had not had time to convene the advisory committee, but that they believed section 15c of the bill, which will allow Zuma to override local patent rights in allowing imports of generic medicines, was "not in compliance" with obligations under the Trade Related Intellectual Property Rights (Trips) agreement.

It was their view the objectives as regards the affordability of medicines as set out in the introduction to the bill and in the general part of section 15c could be achieved in a manner which would not contravene Trips and would fit in with the Patents Act.

The bill, which has also been criticised by the pharmaceutical industry, opposition parties, the Medicines Control Council and the United States government, is to be debated in the NCOP next week. It has already been approved by the National Assembly.

Mirryena Deeb, chief executive of the Pharmaceutical Manufacturers' Association, said her organisation welcomed the advisers' findings as confirmation of what her organisation had been saying all along.

"If this bill is pushed through in the face of this advice from Government's own expert advisers, it will be a major miscarriage of justice and a deliberate attempt by the Departments of Health and Trade and Industry to ignore the truth," she said.

Zuma's spokesman Vincent Hlongwane said the health department got advice from experts at the trade industry department before drawing up the bill. "We have got no reason to believe that the department would mislead its own Government.

"The bottom line is this bill is ensuring cheaper medicines for everybody in this country."

Zuma deliberately misled Parliament on drugs bill, says DP

ARG 15/11/97

PIETER MALAN AND SAPA

Health Minister Nkosazana Zuma's integrity has been called into question by opposition parties after it came to light that she had withheld information from Parliament.

Opposition parties said yesterday Dr Zuma had withheld vital information from the National Assembly's health committee in her quest to bulldoze controversial medicines control legislation through Parliament.

National Party health spokesman, Kobus Gous, said his party wanted to know why Dr Zuma had misled Parliament. His Democratic Party counterpart, Mike Ellis, said the measure, designed to allow the importation of cheaper drugs, should be withdrawn.

The attack on Dr Zuma by opposition parties follows the disclosure this week of a document in which the Government's advisory committee on patents and trademarks said the proposed medicine bill would contravene a major international agreement on intellectual property rights that South Africa had signed.

Advisory committee chairman Judge Chris Plewman and vice-chairperson, Esmé du Plessis, said the Medicines and Related Substances Control Amendment Bill would also violate South African patent law.

'What is Mandela doing about the lack of transparency in his Government?'

Their memorandum – a result of a NP investigation into the matter – was made public this week at a meeting of the National Council of Provinces' social services committee, which debated and approved the legislation.

Judge Plewman and Mrs Du Plessis also confirmed that their committee had given a similar opinion earlier this year on an earlier version of the bill, since withdrawn, and that this was made available to Dr Zuma.

Dr Gous said yesterday that the first opinion had not been forwarded to the National Assembly's health committee, and asked what President Mandela was going to do about the lack of transparency in his Government.

"What is Dr Zuma's real motivation behind bulldozing the bill through Parliament?"

Mr Ellis said it was absolutely unacceptable that Dr Zuma could have had the information, yet not told the portfolio committee.

"I am concerned that the minister has deliberately misled the committee and Parliament," he said. "It would not be the first time she has done it; this latest incident calls her integrity into question."

Judge Plewman and Mrs Du Plessis were approached on November 10 by the legal adviser of the Free State legislature, who asked for their opinion on the bill – then being debated by the province's health committee.

Judge Plewman and Mrs Du Plessis said they had not had time to convene the advisory committee, but that they believed that Section 15C of the bill, which will allow Dr Zuma to override local patent rights in allowing imports of generic medicines from other countries, was "not in compliance" with South Africa's obligations under the Trade Related Intellectual Property Rights (Trips) agreement.

The bill, which has been criticised by the pharmaceutical industry, opposition political parties, the Medicines Control Council and the United States government, is to be debated in the National Council of Provinces next week. It has already been approved by the National Assembly.

'What is her real motivation behind bulldozing this bill through Parliament?'

Mirryena Deeb, chief executive of the Pharmaceutical Manufacturers' Association, said her organisation welcomed the advisers' findings as confirmation of what her organisation had been saying all along.

"If this Bill is pushed through in the face of this advice from Government's own expert advisers, it will be a major miscarriage of justice and a deliberate attempt by the Departments of Health, and Trade and Industry to ignore the truth," she said.

Dr Zuma's spokesman, Vincent Hlongwane, said the Health Department had received advice from experts at the Department of Trade and Industry before drawing up the bill. "We have no reason to believe that the department (of trade and industry) would mislead its own government," he said.

Referring to the advice the minister had received earlier, Mr Hlongwane said: "Who advised whom about what is beside the point. The bottom line is that this bill is ensuring cheaper medicines for everybody in this country."

Row over Zuma's cheap drugs Bill

ST 16/11/97 (96) (183)

CRAIG DOONAN

TRADE and Industry Minister Alec Erwin — and a committee which is meant to advise him and his department on intellectual property rights — are at odds over Health Minister Dr Nkosazana Zuma's new health legislation.

The Medicines and Related Substances Control Amendment Bill will make it easier for South Africans to buy drugs made in India and other countries which do not respect US patents and copyrights.

But, while Professor Esmé du Plessis, the deputy chairman of Erwin's patents advisory committee, has said the legislation contravenes international law, another ministerial adviser, Trevor Abrahams said: "I can confirm it in no way undermines intellectual property rights."

He said the most controversial section of the Bill, Section 15C, "will not violate the intellectual property rights of any drug manufacturer in any form".

But, said Du Plessis, the section did not comply with South Africa's obligations under the Trade and Related Intellectual Property Rights agreement.

"This section of the Bill has the potential of introducing discriminatory mechanisms that are not within the permitted framework envisaged by the Trips agreement," she said.

Du Plessis said that while she supported Zuma's objectives, "this is not the correct way of doing it".

Du Plessis' views are shared by opposition parties, drugs manufacturers and the United States government.

Zuma's spokesman Vincent Hlongwane said yesterday that the Department of Trade and Industry had been directly involved in drafting the clause "and they would ensure they didn't violate agreements which they signed on behalf of the government".

But Du Plessis said yesterday she was surprised that her committee was not consulted on the clauses because it had been set up for this purpose.

Dispensing doctors braced for costly fight

(96)

SHARKEY ISAACS
STAFF REPORTER

ARG 20/11/97

Doctors are taking their fight to dispense medicine to court to stall the presidential signing of legislation limiting this right.

They say litigation is the next step in delaying the signing of Health Minister Nkosazana Zuma's bill by President Nelson Mandela and its subsequent promulgation.

Elaine Clarke, chairman of the Dispensing Family Doctors' Association, said legal opinion had been sought and senior counsel engaged.

Doctors were raising the money for impending costly civil litigation, she said. "We consider it our duty to do this as we alone have to listen to the voices of our patients."

Under the bill, doctors will have to apply for licences to dispense medicine, which will be granted only in areas where pharmacies are scarce.

Because the term "scarce" is open to interpretation, it stops all doctors in metropolitan areas from dispensing medicines and also affects those in country towns where doctors have surgeries near pharmacies. There are pharmacies in almost all residential areas on the Cape Flats.

The bill, passed last month by the National Assembly, may take another six months to become law. Dispensing doctors will then have six months to clear medicine stocks.

If they fail to comply with the law after this period, they face fines running into tens of thousands of rands.

At the annual meeting of the Dispensing Family Doctors' Association, members expressed disappointment at the passage of three health bills.

Delegates found it regrettable that politicians had introduced legislation with such far-reaching implications for the poor without consultation.

Dr Clarke said: "It is sad to see politicians have forgotten where they came from – the people who put them in power and the fact that many of them benefited from the care provided by doctors in their residential areas during the political struggle.

"Many of the family members of these very politicians, as well as the vast majority of their constituency, have expressed anger and disappointment about these laws and continue to depend on all the services rendered by their doctors, for which they are charged a single fee for consultation and medication."

Controversial new health bills approved by provinces

Star STAFF REPORTER

Star 21/11/97

The controversial trio of health bills allowing for parallel importing of cheaper drugs, community service for young doctors and lay ownership of pharmacies has been approved by the National Council of Provinces (NCOP).

The Medicines and Related Substances Control Amendment Bill, the Medical, Dental and Supplementary Health Service Professions Bill and the Pharmacy Amendment Bill have already been approved by the National Assembly and can now be signed into law.

They were opposed in the NCOP only by the Western Cape and KwaZulu Natal.

Health Minister Dr Nkosazana Zuma said she was happy the bills had been passed as they were meant to "shape and reform our health service in a way that will benefit all the people".

Zuma said she would now be able to look at when community service could "realistically" begin. She said she intended contacting the Junior Doctors Association of South Africa next week before going public with her plans.

Anna Sporaco, National Interns Alliance spokesman, said the alliance was prepared to launch legal action "within 12 hours" if the minister announced that community service would be implemented in 1998.

The Medical and Dental Council has already registered some 1997 interns under the 1974 legislation, Sporaco said.

The Medicines Bill, which some believe allows the minister to override patents in order to import cheaper medicines, has been strongly opposed by the pharmaceutical industry, and may be challenged through the World Trade Organisation.

Western Cape NCOP delegate Dr Quarta du Toit said in the debate that the bills were among the most draconian laws ever enacted in South Africa, and sounded the death knell for health-care.

Health department exaggerated medicine prices

Cape Town – Health Minister Dr Nkosazana Zuma's department made grossly exaggerated and misleading claims earlier this year about the relative expense of medicines in South Africa, Public Protector Selby Baqwa has found.

However, in a report compiled after a complaint by the pharmaceutical industry, he made no finding of improper conduct, adding it appeared that pharmaceutical profits in South Africa were "substantial".

The complaint to the public protector was lodged by the Pharmaceutical Manufacturers' Association of South Africa in June this year at the height of its battle with Zuma over her proposed legislation to lower drug prices.

She used claims that South African prices were out of line with other countries to motivate formalisation of generic substitution and a controversial proposal to override patent rights in allowing imports of cheaper medicine.

The legislation, the Medicines and Related Substances Control Amendment Bill, cleared its final parliamentary hurdle last week when it was approved by the National Council of Provinces.

Baqwa said he had appointed a five-person panel of experts to help him in his probe.

He said a statement by the Health Department in March this year, which was later reiterated by Zuma, that South Africa was among the five most expensive countries in the world for medicine, needed convincing data as back-up.

The various documents that Zuma had submitted to substantiate the claim had failed to do so, and it was not easy to rate on a point-scoring method the accuracy of the numerous sources and statistics referred to.

It became quite clear, Baqwa said, that the information had been grossly exaggerated, but added that while the department's statement could be misleading, it was not improper. – Sapa

25/11/97 (96)

Zuma claims misleading, not improper, says Baqwa

ARG 25/11/97

(96)

Drug price probe

Health Minister Nkosazana Zuma's department made grossly exaggerated and misleading claims about the relative expense of medicines in South Africa, Public Protector Selby Baqwa has found.

However, in a report compiled after a complaint by the pharmaceutical industry, he made no finding of improper conduct and said it did appear pharmaceutical profits in South Africa were "substantial".

'Misleading': Dr Zuma

National Party health spokesman Dr Kobus Gous said Mr Baqwa's findings confirmed suspicions that Dr Zuma had misled Parliament and the public.

"We once again ask for her resignation and reiterate our call on the president to reconsider her position in Cabinet."

The complaint to the public protector was lodged by the Pharmaceutical Manufacturers' Association of South Africa in June at the height of its battle with Dr Zuma over her proposals to lower drug prices.

The legislation, the Medicines and Related Substances Control Amendment Bill, cleared its final parliamentary hurdle last week when it was approved by the National Council of Provinces.

Mr Baqwa said a statement by the Health Department – reiterated by Dr Zuma – that South Africa was among the five most expensive countries in the world for medicine, needed convincing data as back-up.

Various documents submitted to substantiate the claim had failed to do so. It was impossible to say that she was either able or unable to back up the statement, and it could be argued that the contrary was true.

"Nevertheless, from the evidence presented, it can be deducted that pharmaceutical profits are substantial in this country; that the cost and price of pharmaceuticals in South Africa is high; and of the premium rand available for health care, the amount spent on medicine is nearly double to triple that of other major countries," he said.

Mr Baqwa said Dr Zuma had conceded that another statement – claiming medicines were 4 000% more expensive than the world average – was based on an erroneous calculation. She had said the figure should have been 2 515%. It also appeared the statement was based on the price difference of only one drug.

It became quite clear, Dr Baqwa said, that the information had been grossly exaggerated.

Another department statement on the low level of prescription of generic medicines in South Africa could be misleading, but was not improper. – Sapa

Zuma exaggerated claims on prices of medicines – Baqwa

Sowetan 26/11/97 (96)

HEALTH Minister Dr Nkosazana Zuma's department made grossly exaggerated and misleading claims earlier this year about the expense of medicines in South Africa, Public Protector Selby Baqwa has discovered.

However, in a report compiled after a complaint by the pharmaceutical industry, he made no finding of improper conduct.

He said it appeared that pharmaceutical profits in South Africa were "substantial".

National Party health spokesman Dr Kobus Gous said in reaction that Baqwa's findings confirmed suspicions that Zuma had misled Parliament and the public at large.

It was inconceivable that an unsuspecting public was fed wrong and exaggerated information on such an important issue as health.

"We once again ask for her resignation and reiterate our call on the President to reconsider her position in the Cabinet," Gous said.

The complaint to the public protector was lodged by the Pharmaceutical Manufacturers Association of South Africa in June this year at the height of its battle with Zuma over her proposed legislation to lower medicine prices.

She used claims that South African prices were out of line with other countries to motivate the formalisation of generic substitution and a controversial proposal to override patent rights in allowing imports of cheaper medicine.

The legislation, the Medicines and Related Substances Control Amendment Bill, cleared its final parliamentary hurdle last week when it was approved by the National Council of Provinces.

Baqwa said he had appointed a five-person panel of experts to help him in his probe.

He said a statement by the Health Department in March this year, which was later reiterated by Zuma, that South Africa was among the five most expensive countries in the world with regard to medicine prices, and needed convincing data as a back-up.

The various documents that Zuma had submitted to substantiate the claim had failed to do so, and it was not easy to rate on a point-scoring method the accuracy of the numerous sources and statistics referred to.

It was impossible to say that she was either able or unable to back up the statement. – *Sapa.*

the possibility of compensation. While resources are naturally finite, sentencing could include a compensation order to the convicted criminal. "Laws must be victim-friendly," De Lange says. Community volunteers to comfort and counsel victims would help humanise the trial experience;

- Eliminating night sittings in bail applications — not least on cost grounds — and limiting the availability of dockets to accused persons until they actually come to trial — a measure designed to safeguard witnesses; and
- Eliminating abuses in debt collection and maintenance payments. In the latter case, defaulters will find their employers served with what would amount to garnishee orders on their salaries.

The new bail law is intended as an integral part of the reform process, but it has been "misconstrued" by some, De Lange says. He points to one major intended effect — the prioritisation of 10 serious crimes (murder, rape, armed robbery and so on) in such a way that any judicial officer will have to consider whether a suspect is denied bail, or a convict receives a minimum sentence.

***De Lange** . . . striving to transform the justice system*

It is in bail and sentencing that inconsistencies are most marked within the current justice regime. De Lange points out that Omar daily receives pleas to "do something about crime," which is not, strictly speaking, his remit. However, by putting 10 "priority" crimes into bail and sentencing law, the judge will be compelled to become aware that a policy — rather than a departmental exhortation — is at work.

This does not remove all discretion from the judicial officers. But in allowing bail, or deviating from a minimum sentence, the reasons must be there for higher review.

Peter Wilhelm

HEALTH MINISTRY & THE PUBLIC PROTECTOR

(96)

Baqwa wields wet noodle

No censure for Zuma, despite finding she misled the public

FM 28/11/97

Health Minister Nkosazana Zuma has little to fear from the Public Protector's report on the truthfulness of her department even though it finds that the department disseminated erroneous, grossly exaggerated and misleading information to support her contentious drug reforms.

The report does no more than rap the department's knuckles, while effectively condoning the dissemination of inaccurate information by government as the legitimate exercise of free speech.

"This is no surprise since the Public Protector, Selby Baqwa, has a long association with the ANC," says IFP MP Ruth Rabinowitz. "It is unfortunate that he has a record of sheltering ANC Ministers from accountability."

In June the Pharmaceutical Manufacturers' Association (PMA) asked Baqwa to prevent parliament from considering the Medicines and Related Substances Amendment Bill until he had investigated the veracity of international drug price comparisons quoted by health officials in support of it. After several delays, Baqwa released his findings last week — the day after parliament passed the Bill.

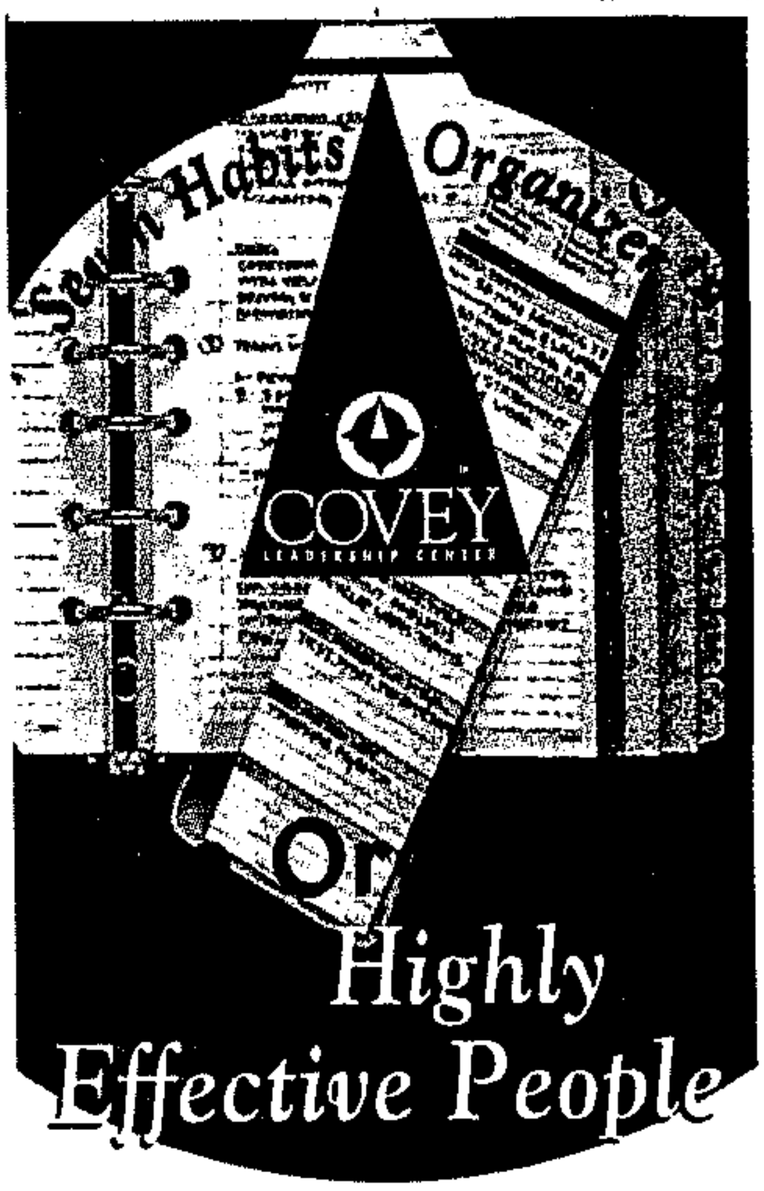
He finds one of the disputed statements was wrongly attributed to the department. Of the remainder, though, he finds one is "grossly exaggerated", two are inaccurate, two could be misleading and two are based on inappropriate price comparisons.

PMA CEO Mirryena Deeb says she is outraged that the findings were not released in time to inform debate around the Bill. The PMA and 30 drug companies are preparing a Constitutional Court challenge to have the Bill set aside.

The NP is again calling for Zuma's resignation and appealing to President Nelson Mandela to not sign the legislation. It planned to table a motion in parliament this week calling for a debate on the issue.

"It is now apparent that the department did not conduct the debate over the Health Bills in a considered or rational way but waged a propaganda war based on deliberate disinformation," says DP MP Mike Ellis. "We are now left with flawed legislation based on flawed research."

Claire Bisseker



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Beyond Time Management This Is Life Leadership!

Zuma plans to overrule MCC

Sowetan 2/12/97

By Mokgadi Pela

HEALTH Minister Nkosazana Zuma is planning to forge ahead with a law that will enable patients to use drugs of their choice if it means saving their lives.

Speaking to journalists yesterday at a media briefing at Odi Stadium, north of Pretoria, where she had just addressed a World Aids Day rally, Zuma said: "One day I will have the power to overrule the Medicines Control Council (MCC)."

She was referring to the power the MCC has to refuse medication to patients such as the controversial Virodene PO58, even on compassionate grounds.

"There should be no one on earth, not even the president of the country, with powers to refuse patients the right to use drugs of their choice if it will make a difference to their lives. But in this country surprisingly, the MCC has such powers," Zuma said.

She added that it "breaks my heart to see the number of letters I receive from patients who are dying wanting Virodene to be administered to them. I often cry in my office as I feel powerless. I am, however, convinced that one day I will have an enabling law that will allow me to overrule the MCC.

"Please get me correct. I'm not making a case for Virodene," Zuma said.

The MCC prohibited Virodene trials on Aids patients, saying the drug caused liver cancer because of toxic ingredients. It (the MCC) said not enough subjects had been tested to prove the efficacy of the drug.

The rally had been called to launch, with the Department of Education, a life skills programme.

The project aims to specially train about 13 000 teachers nationally by April 1998.

The training programme will feed into Curriculum 2005 and will not only inform, but will empower learners with skills, attitudes and values in order to make informed choices.

● The African National Congress Youth League yesterday appealed to Zuma and the MCC to explore the testing of various drugs, including Virodene. "We owe it to the infected people to test whether the drugs work or not. Lives must be spared," the ANCYL said.

Zuma sees role for trial drugs

BD 5/12/97 (96)

Josey Ballenger

HEALTH Minister Nkosazana Zuma was thinking of introducing legislation to allow critically ill patients "compassionate" access to unregistered medicines, spokesman Vincent Hlongwane said yesterday.

The issue — which first came to public attention on Monday when Zuma said that dying AIDS patients should not be prevented from using the unapproved drug Virodene — has arisen due to the lack of a cure for the human immune deficiency virus (HIV).

Hlongwane said Zuma was "not making a case specifically for Virodene", a potentially toxic drug which has been rejected three times by the Medicines Control Council, and that her comments should be seen "in context ... There are patients who are dying and who strongly believe Virodene can help them. She wants to help people prolong their lives. Her main concern is that we do not have an alternative for these people."

An interim court interdict has been granted against the trade, dispensing or further development of Virodene until a hearing in the Pretoria Supreme Court next Tuesday, and the SA Police Service is investigating alleged illegal use.

Hlongwane said Zuma was looking at introducing legislation "with very clear parameters" to allow doctors to prescribe unapproved drugs to accommodate "the last wish of a dying person". much as the US and the UK had done.

UK and US authorities confirmed they had laws to this effect. A UK Medicines Control Agency official said a doctor could prescribe an unregistered drug in cases where a patient had a "special need" — interpreted to mean there is no equivalent licensed product — and where the doctor "takes responsibility" for the drug's performance.

Since 1987, the US Food and Drug Administration has permitted the use of unapproved, "investigational" products to treat patients with "serious or immediately life-threatening diseases" under certain conditions including a patient's "informed consent".

However, in both countries, in cases where authorities considered a drug dangerous, they would rule that the product not be used.

Medicines Control Council chairman Prof Peter Folb said he did "not believe there is a single person, no matter how kind or compassionate, who can make this kind of decision (prescribing unapproved drugs) alone".

Folb also said he would "welcome" legal action by Virodene researcher Olga Visser and her husband Zigi, who have reportedly threatened to take action against the council.

People with 'core competencies' sought

(96) BD 12/12/97

Josey Ballenger

CERTAIN members of the Medicines Control Council (MCC) would be replaced by next May with individuals who represented an updated list of "core competencies", Health Minister Nkosazana Zuma announced yesterday.

Zuma said regulations to be promulgated next year would change the base of experts outlined in old legislation— for example, they may add a lawyer and toxicologist — and replace those members who had served on the drug regulatory body for more than 10 years.

Such regulations would lead to the replacement of council chairman Prof Peter Folbs and several other members who have served for longer than a decade.

Zuma said her department was discussing the regulations, to be promulgated with regard to parallel drug importation and which had been the subject of heated public debate, with leading pharmaceutical companies. She said she was "quite confident" they would be satisfactory.

The Medicines and Related Substances Control Amendment Bill was "not a patent-busting law, but it will allow us to meet our objectives (of providing cheap medicine). We are not fighting industry; we need them." She said the department was also working on regulations regarding the ownership of pharmacies under the Pharmacy Amendment Bill, which was also approved by Parliament last month.

Regarding the unapproved anti-AIDS drug Virodene — which the MCC agreed last week to evaluate for a fourth time with new clinical trials — Zuma said she held the "same position as earlier this year", which was "to support every research effort that may give us a glimmer of hope in terms of AIDS. At the moment, no one knows if (Virodene) works."

Zuma reiterated earlier reports that she supported "compassionate" use of unapproved drugs, but emphasised that neither she nor the MCC had exercised available legal options in allowing even controlled dispensing of the drug.

"I did not support illegal use," she said in reference to recent allegations of illegal Virodene use.

She said were compassionate use to be invoked, it would involve controlled, named-patient conditions. "It does not mean the wholesale use" of a drug.

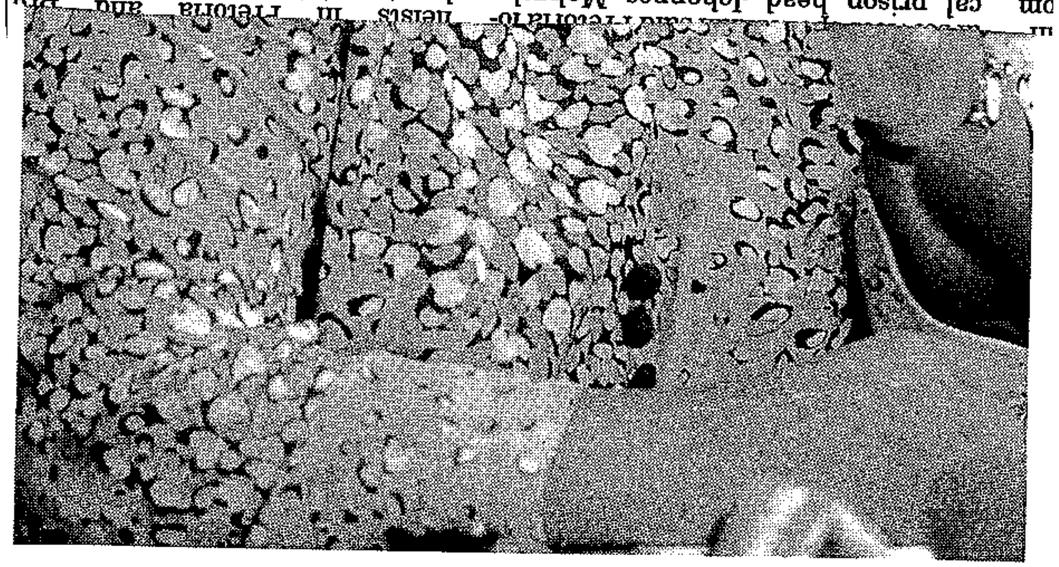
On the subject of AIDS, Zuma believed the fatal immune deficiency disease should be a notifiable condition to sexual partners and families, as well as to government. In the case of government, notification would be anonymous, as it was with abortions, maternity-related deaths and other notifiable conditions.

Zuma said Deputy President Thabo Mbeki would head a "mass mobilisation" programme of action to fight AIDS, which would report to cabinet. The programme would aim to demystify and thus destigmatise the disease, and would target children, women, and people who engaged in risky sexual behaviour, such as migrant workers, politicians, pilots, the military, businesspeople and truck drivers.

At the same time, government had to deal with discrimination, or "secrecy and stigmatisation" would persist.

Zuma said the department would introduce legislation in Parliament's next session on medical aid schemes, national health insurance, public health system and tobacco. Regarding tobacco, Zuma said government would target education towards youths and women, as few smokers started after the age of 20, and the tobacco industry was now aiming to entice women, who have historically smoked less than men, as customers.

In addition, she said that the legislation would likely bar tobacco companies from sponsoring sports events, and would recognise that "nonsmokers have rights", which might mean banning smoking in public areas.



Health Minister Nkosazana Zuma addresses reporters on health policies and programmes at a news conference in Johannesburg yesterday. Picture: TYRONE ARTHUR

High Court bans

cal prison head Johannes Makgoba faced suspension — unless he could give reasons why such action should not be taken against him — for allegedly taking a R100 000 bribe. Makgoba had until today to respond. Eight other prison officials had received similar notices. This follows the escape of six dangerous prisoners last Friday from Pretoria local prison, which is next to Pretoria central prison.

horsfruit involving millions of ran

Potgieter said Makgoba was give letter of intended suspension earlier the day after two awaiting-trial p oners alleged he had receiv R100 000 for giving a gun to a prison But he said the department suppor fair labour practices and would summarily suspend staff membe without considering all the facts.

The eight other officials were bei

Zuma's health bills come under fire from industry

BD 31/12/97

Ingrid Salgado

THE pharmaceutical industry has again expressed concern over Health Minister Nkosazana Zuma's controversial package of "health bills" passed through Parliament recently, saying that the introduction of parallel imports could lead to an influx of counterfeit and substandard drugs.

This time the warning comes from Robbie Williams, chairman of locally listed pharmaceutical group Adcock Ingram. In the company's latest annual report Williams said the benefits flowing from parallel imports of cheaper medicines were "questionable".

Failure to subject parallel imports to the same rigorous controls as locally manufactured products could lead to a barrage of second-rate medicines, he said. A "major concern" was the vagueness of the legislation and wide powers vested in the health minister to regulate health care without following the parliamentary debate process.

The Medicines and Related Substances Amendment Bill and the Medical, Dental and Supplementary Health Service Professions Amendment Bill passed their last legislative hurdle last month when they were approved by the National Council of Provinces. The laws seek, among other things, to lower drug prices by introducing parallel imports and encouraging the use of generic drug substitutes.

Zuma has stated that parallel imports would take place only under defined conditions and regulations.

Williams said Adcock Ingram was better positioned than most competitors to deal with changing conditions and effects of the legislation owing to a strong position in the hospital products and over-the-counter markets.

Adcock Ingram, emerging from a major restructuring after last year's merger with Premier Pharmaceuticals, had several key strengths that reduced its risk profile, he said.

Among these were a wide portfolio of powerful brands in both branded and generic prescription products, flexible and cost-effective manufacturing facilities, a focused research and development programme, a R645m cash pile — "our strong cash position places us in a favourable situation to expand by acquisition", he said — and skilled management.

Williams said Adcock Ingram had had its fair share of uncertainty and disruption following the merger. The restructuring had included the merging and centralisation of service functions, closure of the wholesale division and rationalisation of manufacturing operations from nine to five factories.

However, good management had ensured the process had been relatively quick, and benefits had started to improve the bottom line in the second half of the year to September.

Cost savings resulted from operational synergies, increased critical mass and improved manufacturing efficiencies, leading to a 27% increase in headline earnings to 124,3c a share.

Williams expected further savings in the current financial year. These would be enhanced by the planned closure of the Industria pharmaceutical factory in the course of the year.

HEALTH & DISEASE

- PHARMACISTS -

1998 - 1999

Picture: JON HRUSA

FEELING CAUTIOUS . . . Jean-Rene Fourtou sounds a warning on the possibility of counterfeit drugs being imported into South Africa

Rhône-Poulenc sickened by medicines Bill

(96)

The pharmaceutical company says it will not invest in new products in SA if its patent rights are infringed, writes DON ROBERTSON

ST(BT) 11/1/98

FRENCH-based Rhône-Poulenc, the largest pharmaceutical company operating in Africa, has added its weight to the growing number of international groups which have condemned the passing of the Medicines and Related Substances Control Bill last October.

The Bill will allow the Department of Health to import cheaper, generic drugs for public hospitals and will effectively infringe on the patent rights of international pharmaceutical groups.

Jean-Rene Fourtou, chairman and chief executive of Rhône-Poulenc, currently on a visit to South Africa, says that if the company's intellectual property rights are infringed, "we will not be prepared to invest in new products here, especially in the agricultural sector".

Fourtou is accompanied by vice-chairman Jean-Marc Bruel.

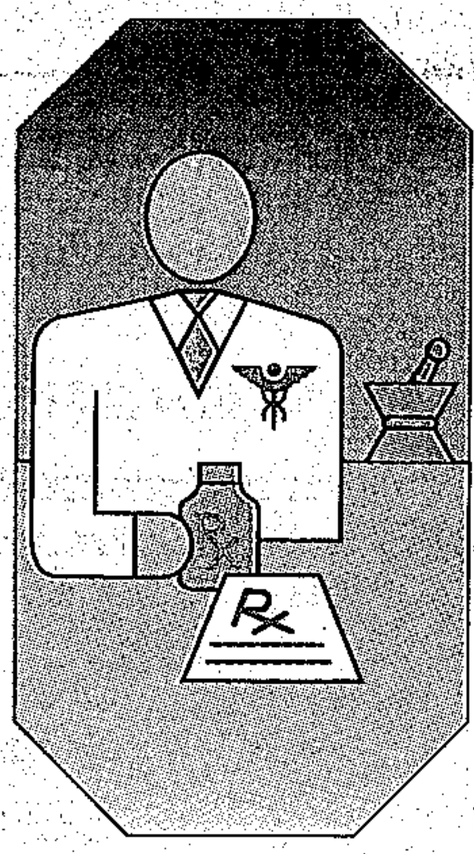
Rhône-Poulenc Agrichem holds third spot in the crop protection industry in South Africa with an 11% share of that specific market.

The group, the world's seventh-largest pharmaceutical company, has been in South Africa since 1931 when it operated as Maybaker. In the past few years, the SA market has been used as the launch-pad for a number of products, including treatments for breast and non-small cell lung cancer, a therapeutic innovation for colorectal cancer and an accompaniment to chemotherapy.

"In the past, if a product was suitable for local conditions, it would be made here. South Africa is a country that has its own problems as a large number of people do not benefit from proper health care.

"It is a country, therefore, that should participate in global technology from developed countries and respect the Trade Related Intellectual Property agreement of the World Trade Organisation," says Fourtou.

He says that other countries such as China, Brazil and India have introduced similar legislation, but have not yet implemented it and he queried the savings that could be effected as only 7% of drugs used in general health care were patented products.



He also warned of the possibility of counterfeit products being imported and pointed to the number of unscrupulous dealers in South Africa.

Rhône-Poulenc describes itself as one of the leading companies in the life sciences field in this country, including pharmaceuticals as well as plant and animal health, with annual turnover of more than R500-million, employing 330 people.

In the financial year to December the group had total sales of Ff85.82-billion, of which 2.5% was generated in Africa and 70% of this in South Africa.

With a 32% share of the world vaccine market, Fourtou believes growth in Africa is vital.

New automation of pharmaceutical testing has allowed research groups to achieve more in one year than in the previous 100 and Fourtou is optimistic that with the speed-up in the process cures for cancer and AIDS will be discovered within the next 10 years.

Those who object say strong concentrations of the chemical can be damaging, not beneficial

Fluoride and our water: it's up to Zuma

Star 26/1/98 (96)

By Priscilla Singh
Health Reporter

Draft regulations to introduce fluoride into the public water supply have already been approved by three ministries, and the Department of Health hopes that fluoridation will become a reality before the end of the year.

Fluoridation is the controlled increase of the fluoride concentration in a public water supply by adding fluoride compounds. This has to meet the standards of the Department of Health, for maximum health benefits.

The Health Department has come out strongly in favour of the fluoridation of public water supplies and a National Fluoridation Committee was set up by Health Minister Dr Nkosazana Zuma with the purpose of ensuring that all communities have access to appropriate sources of fluoridation.

It has so far received the blessing of the Departments of Water Affairs and Forestry, and Environmental Affairs and Tourism.

The Health Department says fluoridation remains the most equitable, safest, most practical and cheapest way to improve dental health. Already three compounds – sodium fluoride, fluorosilicic acid, and sodium fluorosilicate – have been approved for use.

Dr Johan Smit, from the national oral health directorate, says the committee had drawn up draft regulations on fluoridating public water supplies in SA and these regulations, once approved by Zuma and gazetted, would be promulgated in terms of the existing Health Act. After appearing in the Government Gazette, the regulations will be open for public scrutiny and comment for three months.

The draft regulations are expected to be mandatory, and criteria for the exemption of local authorities from fluoridating public water supplies have also been drafted, as have technical specifications for implementing water fluoridation.

In the absence of a national regulatory framework, water authorities have been reluctant or unable to introduce water fluoridation.

The draft legislation says the water provider must inform all local authorities to which it supplies drinking water that the public water supply will be fluoridated.

In considering an application by a water provider to register with the Department of Health for setting up a fluoridation plant, the director-general will consider the level of dental caries, or decay, in the supply area of the water provider, the population in the area, the estimated per capita costs of fluoridation, and the feasibility of using alternative fluoride supplements.

Three elements are seen as necessary for successful fluoridation, namely the level of fluoride in the raw water, the community which will be drinking it, and specific resources such as staff, equipment, chemicals and finance.

If the raw water available to a supplier already contains the optimum amount of fluoride, then fluoridation is unnecessary and should not be undertaken. Also, if raw water is available to a supplier intermittently, then the department advises strongly against fluoridation.

If the community has few people with tooth decay, the department does not think it necessary to introduce fluoride into the water supply, the draft legislation states.

The 1997 South African Health Review (SAHR), agreed with the department that the addition of fluoride to the public water supply was cheap.

Calculations on the cost of fluoridating the water supplies of Port Elizabeth showed that the cost per person per year would be R1,28. It also showed that fluoridated water was 18 times less expensive than toothpaste and 61 times less expensive than having a tooth filled.

Cheap way to oral health, says department

But is it healthy?

Fluoridation reaches everybody in the community, a feature which is both its greatest strength and its greatest problem in terms of social policy, says Usuf Chitke of the Department of Community Dentistry at the University of Stellenbosch.

Considerable media attention has been given to fluoridation, highlighting the general lack of understanding, and opposition to fluoridation has centred on claims of risk to the environment or human health.

Chitke says that while these arguments had a weak scientific base, it nevertheless had strong emotional appeal.

"Despite the strong media coverage, less than a quarter of South Africans have heard or read about fluoridation, and only about 25% can correctly identify the purpose of water fluoridation.

"However, whatever the levels of knowledge or sources of information, more than 60% of South Africans favour the adoption of water fluoridation if it can reduce tooth decay," he says.

Earthlife Africa is totally opposed to fluoridation of the water supply and its Johannesburg spokesman Vanessa Black says the organisation's objection is in keeping with the worldwide controversy around both the safety of adding fluoride to drinking water and its efficacy in preventing tooth decay.

It says that fluoridation proponents claim that a concentration of 1 part per million (ppm) of fluoride in drinking water was beneficial – 1ppm equates to 1mg/litre of water, and just 20mg of fluoride per day can cause chronic poisoning.

Black says fluoride accumulates in the water system over time, especially where water is recycled.

"Fluoride is already building up in our water system from toothpaste, industrial effluents and run-off from agricultural land. This will lead to the eventual contamination of scarce water resources.

"Furthermore, it is impossible to control the actual quantity of fluoride an individual will ingest because individuals drink different amounts of water and ingest varying quantities of other foods and substances containing fluoride," Black says.

Fluoride is concentrated in green leafy vegetables and tea. Using fluoridated water in food processing concentrates the amount of fluoride in the food.

What is safe and beneficial to a person depends on body weight, their diet and individual sensitivities to chemicals.

"Fluoride is more likely to adversely affect people whose diet is inadequate, yet these are the same people that water fluoridation is claiming to help," Black says.

In other words, says Black, the authorities intend uniformly medicating the entire population with a chemical substance, which is poisonous in strong concentrations, where they will not be able to control the amount of fluoride being ingested by individuals with differing sensitivities.

"The medical profession would not allow uncontrolled dosing of any other medication, or even vitamins, so why should a controversial chemical like fluoride be administered in this way?" asks Black.

Earthlife believes that fluoride pills should be made available to those who choose to take fluoride, because the amount of fluoride which is ingested can be controlled and individual reactions to this chemical can be monitored.

Despite the debate, Zuma, as Minister of Health, has the authority to implement it, with the backing of the Health Act.

Suppliers must implement fail-safe measures

Before a water provider implements fluoridation it must, within 12 months of the promulgation of the regulations, submit its application for registration in duplicate to the director-general of health.

The water provider must inform all local authorities to whom drinking water is supplied that the water will be fluoridated.

The water fluoridation plant must be of such a design and capability that it incorporates fail-safe and alarm arrangements to prevent overdosing the water supply as a result of a breakdown or malfunction, or a change in the flow rate of the fluoridated water.

Every necessary step must be taken to ensure that the water is fluoridated for at least 90% of the time, and only a fluoride compound approved by the director-general, and adhering to the quality specifications of the Department of Health, be used.

Once a water provider's application is approved, it has to implement fluoridation within two years. If a water provider wants to change the optimum fluoride concentration, it must apply in writing to the director-general.

The director-general can, at any time, authorise an officer from the Health Department, or provincial government, to inspect the plant.

The fluoride concentration of water leaving the fluoridation plant will be monitored by a continuous recording device calibrated every 24 hours, and fluoridated water will be sampled every four hours using analytical procedures laid down by the health department.

The fluoride monitor must be linked to an alarm system and automatic fluoridation plant shutdown, in order to stop fluoridation when the fluoride exceeds 1,5mg fluoride per litre for more than five minutes.

In the event of accidental over-fluoridation (greater than 10mg/l) for any length of time, or a major spill, the water provider must inform the provincial health authority, the director-general, the director-general of Water Affairs and Forestry, and water users immediately.

Any organisation or local authority who is against fluoridation of the water supply can appeal in writing to Health Minister Dr Nkosazana Zuma.

Govt expects drug law to be tested at WTO soon

BD 2/2/98 (96)

Josey Ballenger

PARALLEL drug importation provided for in recent legislation would be "put to the test" as soon as the pharmaceutical industry found a sponsor nation willing to take government to the World Trade Organisation (WTO), a senior health department official said last week.

"If the industry loses, it will set a precedent and be a very good thing for developing countries," said Bada Pharasi, the department's chief director of registration, regulation and procurement.

He said the parallel importation clause was "an enabling one" which would be used only when an essential product was "unjustifiably" more expensive in SA than elsewhere.

"If, as the multinationals insist, our SA prices match the best in the world, it will not be necessary to resort to clause 15C at all," Pharasi told delegates at a health care symposium in Midrand organised by the Institute for International Research.

Threatened

Whether the clause in the Medicines and Related Substances Control Amendment Act constituted a violation of the WTO's treaty on intellectual property was a matter of debate, he said.

The US government, multinational pharmaceutical companies and the local Pharmaceutical Manufacturing Association have threatened in recent months to take legal action against SA, pending regulations to be published in terms of the legislation.

Pharasi said the department's efforts to lower drug costs came nearly 20 years after government had identified the need to do this.

He said a 1978 commission of inquiry into the pharmaceutical industry had focused on "problems arising from public perceptions about the high cost of medicines in SA's private health care sector, complaints in the market about the effects of discriminatory pricing, bonusing, dispensing by medical practitioners (and) irrational prescribing".

These had eventually received the attention of various government departments or bodies.

The policies underlying the legislation were therefore "not entirely new. The difference between then and now can be explained by the presence of political will in the present administration," he said.

Congressmen call for action against SA's medicine act

Simon Barber

WASHINGTON — Forty-five congressmen and two senators have signed a strongly worded letter to US Trade Representative Charlene Barshevsky calling for action against SA's new medicines control act.

The letter, delivered on Wednesday, urges a so-called "special 301" investigation into whether the act violates SA's copyright protection obligations under World Trade Organisation agreements, and if that does not produce results, the filing of a complaint directly with the organisation.

Pharmaceutical Research and Manufacturers of America, the US industry lobby, has already asked the representative to highlight the SA legislation in its annual report on foreign barriers to US trade as a preliminary step to seeking formal action, and ultimately retaliation, under section 301 of the US trade act.

SA's only previous brush with "special 301" was over the SA trademark rights of fast-food company McDonald's.

The bipartisan congressional initiative was spearheaded by New Jersey Congressman Robert Menendez, the senior Democrat on the House Africa subcommittee, and strongly supported by the rest of his state's delegation. Pharmaceuticals are New Jersey's largest industry.

The letter is seen as stepping up the pressure on both the SA government and the US administration to resolve the matter when the US-SA Binational Commission, chaired by US Vice-President Al Gore and SA Deputy President Thabo Mbeki, holds its next meeting in Cape Town later this month.

US drug companies are up in arms over a clause in the SA act that they say gives the health minister carte blanche to abrogate their patent rights. The firms are also angered that the legislation permits their patented products to be imported outside their own marketing channels and pricing structures.

There is debate within the administration over whether to declare an official dispute before President Bill Clinton's planned state visit to SA at the end of March.

It remains unclear, however, as to whether the companies' complaints can be resolved without rewriting the legislation. Some argue that a compromise could be reached through the wording of the regulations implementing the law.

Fluoridation bill will bring smiles to faces of the disadvantaged

(96) Star 6/2/98

By Xolisa Vapi

Disadvantaged communities will reap the benefits of the Fluoridation of Drinking Water Bill, set to become law by the end of the year, which will compel water suppliers to add fluoride to the public water supply to reduce levels of tooth decay.

The Departments of Water Affairs and Forestry, Environmental Affairs and Tourism, and Agriculture have come out strongly in favour of this new "preventive medication" legislation, which will benefit thousands of downtrodden South Africans who have been denied primary health care for years.

The Health Department said yesterday that water fluoridation would start in major metropolitan areas: "They (newly urbanised people) are now exposed to the danger of dental decay due to increased levels of sugar consumption," department oral health director Dr Johan Smit said.

According to Smit, more than 90% of adults in South Africa, especially those in poor communities who could not afford oral health services, were experiencing tooth decay.

"While everybody will benefit from fluoridation, children are the ones who will reap the greatest benefits," said Smit.

He said while there was no difference between the fluoride in natural drinking water and fluoride added to the drinking water, it was vital to fluoridate public water as 70% dental decay in 6-year-olds would reach 90% when they become adults.

The opponents of the new legislation are convinced that water fluoridation is a waste of money and time as there is enough fluoride in water and too much may damage one's bones and teeth.

But Smit said there was scientific evidence that fluoridation adjusted the amount of fluoride present in natural water to the best level and prevented tooth decay by up to 60%, adding that the facility would cost a person R1 per year.

Zuma vows drug fight

(96) (189) ARG 26/2/98

The Government will fight legal action by the Pharmaceutical Manufacturing Association (PMA) to have the Medicines and Related Substances Control Amendment Act declared unconstitutional, Health Minister Nkosazana Zuma says.

"The Government is concerned that the legal action by PMA will delay the implementation of the legislation, which is aimed at improving the lives of all South Africans," she said in a statement yesterday.

The PMA and 41 co-applicants in the court action say the act violates the constitution by giving Dr Zuma wide powers to override the Patents Act.

However, she maintains she needs this power to allow parallel imports of cheaper medicines.

The United States drug industry on Tuesday asked the Clinton administration to formally declare South Africa a major violator of intellectual property rights unless the Government agreed to amend the Medicines Control Act, Business Day reported yesterday. – Sapa

Students find rural service plan a bitter pill to swallow

Many face mounting interest on loans

ARG 17/3/98 (96)

ANDREA BOTHA
STAFF REPORTER

LEON LESTRADE

Test tube students: Hybre Reeding is uncertain of the implications of community service

Hybre Reeding is a final-year pharmacy student at the University of the Western Cape.

She has just married and is still on her honeymoon. She is one of many students opposed to proposed community service for pharmacists.

She has another year as an intern ahead of her, after which she has to work off her bursary for a year.

If she has to do a year of community service, it will be three years before she can earn a living or contemplate having a family.

The Government is looking at a proposal for a national community service scheme that would require graduates like engineers, lawyers, architects, accountants and dentists do a year of community service in poor communities.

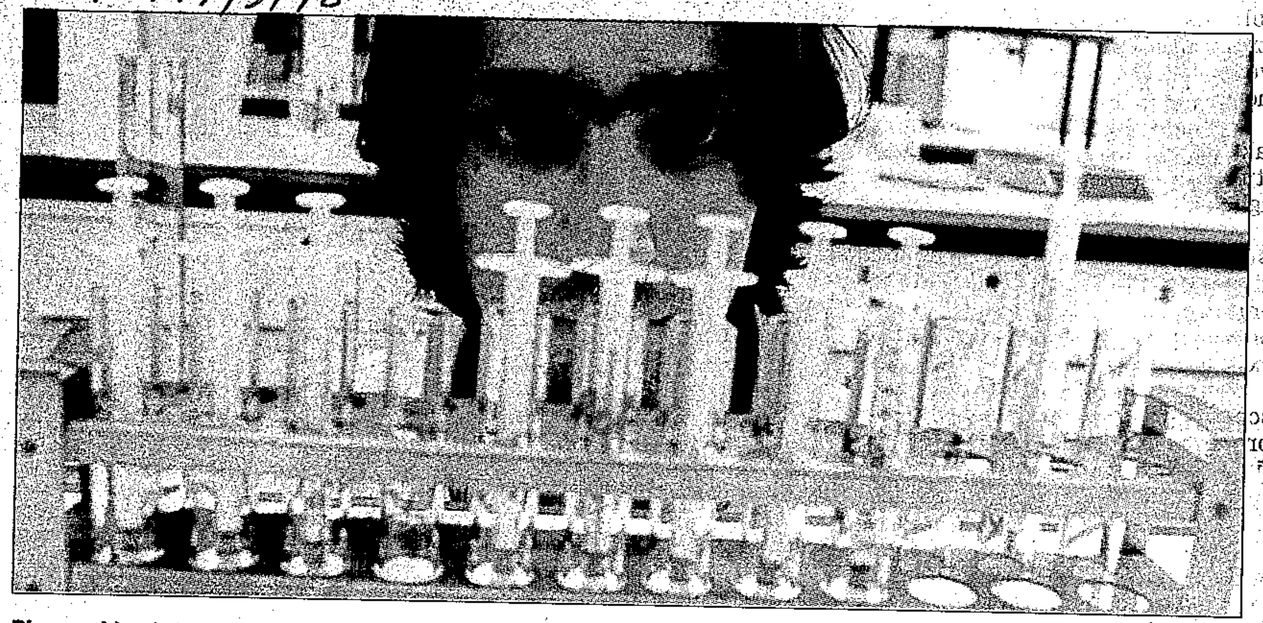
Compulsory national service for graduating doctors starts in July and Health Minister Nkosazana Zuma has said the service is likely to be extended to pharmacists and dentists.

But few pharmacy students at the UWC are in favour of the plan.

Naushaad Ebrahim, chairman of the University of the Western Cape Association of Pharmacy Students, said a survey had been conducted among second-, third- and fourth-year students and most disapproved.

"The students feel they won't have a choice of where to go, and that the year would only be a duplication of their internship year."

Few students disagreed with community service itself, but with the way it would be implemented. They felt they did not have a choice about their postings and said they were not consulted about working conditions.



Dispensable: chairman of the UWC Association of Pharmacy Students Naushaad Ebrahim says most students disapprove of the plan

Many of them had bursaries and loans to work off, and some were married with families to support.

Pharmacy students had to study for four years and work as interns for a year to get their B Pharm degrees. From their second year, they worked within communities and with primary health care.

"Going out into rural areas without supervision will not benefit anybody, " said final-year student Sabier Marthinus, adding that interest would mount up the longer he did not repay his loan.

"Rural areas do need community services, but I don't agree with the conditions under which we are supposed to work," said Najma Solomon, also a final-year student.

Praneet Valodia of Pharmacy Practice at the university said he was in favour of community service for pharmacists, but would like to see it as part of their internship and training.

"Pharmacists do not just dish out pills, but are involved in primary health care," he said.

Patients in many rural areas, often saw pharmacists before they saw doctors as they were more accessible and their advice was free.

They sold over-the-counter medicine and did blood pressure tests, cholesterol and diabetes screening and even provided contraception services.

Peter Eagles of the department of pharmaceutical chemistry said all training should be done in the community anyway, but he would like to see universities involved in developing the best models for community service. He also believed it should be part of the undergraduate training course.

Dr André Dreyer of the department of dentistry at Stellenbosch University said there was obviously a need for community service, but he was uncertain about whether structures were in place to accommodate dentists. He said community service went hand in hand with training.

exclude govt bodies

Bank governor Chris Stals said in his monetary policy statement this month he would like to see the rate of growth in credit come down to 10%.

Stals said last week he believed a new definition of private sector credit would make sense and he was pleased that the revised credit growth rate was not far off the levels he wanted to see.

The new definition excluded loans to local authorities but included loans and advances under resale agreements to "other parties" and foreign finance on-lent to clients.

According to central bank figures, bank loans to local authorities have risen from R1,4bn at the end of 1996 to R3,4bn at the end of last year — a growth rate of about 143%.

Local authorities' borrowing has been cited as one of the reasons why private-sector credit growth has defied gravity, despite high real interest rates.

Another reason noted by economists is the explosion of trading activity in the SA financial markets.

A recent example of the way in which the financial markets can influence the credit aggregates was the Business Bank listing, an economist said. The bank's listing was more than 63 times oversubscribed, raising more than R3bn. Much of that finance for share applications would have been borrowed, and would show up in the credit numbers.

Ernie van der Merwe, special economics adviser to Stals, said that the monetary aggregates were probably influenced by popular new listings. "But it would be very difficult to quantify how much."

He said one could not assume that the entire amount had been borrowed, but some of it probably had been.

United Democratic Movement co-leaders Roelf Meyer and Bantu Holomisa address a news briefing in Johannesburg yesterday, at which they claimed state oil reserves had been sold off to below minimum levels in order to balance the budget. Picture: ROBERT BOTHA

Clinton pressed to tackle medicine control act in SA

(185)(96)

WASHINGTON — Members of Congress yesterday pressed Assistant Secretary of State for Africa Susan Rice for assurances that President Bill Clinton would use his approaching state visit to SA to insist on changes in the Medicines and Related Substances Control Act, which the US drug industry had termed an "egregious" threat to its patent rights.

Congressmen Ed Royce, chairman of the house Africa subcommittee, and Robert Menendez, the panel's senior Democrat, took turns questioning Rice on the issue at a hearing called to preview Clinton's six-nation Africa tour, which starts on Sunday.

Both members are expected to be part of the president's delegation.

Rice replied that the administration, while supporting the act's goal of cheaper medicine for low-income South Africans, was "concerned about the means".

BD 18/3/98

If the president did not himself raise the subject while in SA, Commerce Secretary William Daley — who is accompanying him — would.

Menendez also sought an undertaking that the US would file a formal complaint against SA in the World Trade Organisation on the grounds that the act violated the body's obligations to protect intellectual property.

"That decision has not yet been made," Rice said.

"We're still looking for common ground. If that's not possible, and it may not be, the US trade representative will weigh the pros and cons."

Pharmaceutical Research and Manufacturers of America (PhRMA), the US drug industry lobby, has petitioned the US trade body to place SA on its "priority watch list" of intellectual property violators, due out in April. That could lead to SA being denied the increased duty-free access to the US market both Congress and the administration are proposing for reform-minded African countries.

Go-ahead for wool levy sought to raise R20m IWS membership

Wyndham Hartley (3) WOOL

CAPE TOWN — The National Agricultural Marketing Control Council has asked permission to raise about R20m through levies on wool to ensure continued membership of the International Wool Secretariat (IWS).

If the application fails to win the backing of the two parliamentary agriculture committees, garments made from SA-grown wool would not be able to carry the international woolmark.

Eugene Brock of the marketing council said yesterday his submission to Parliament's agriculture committee had been received positively. He said the levy, 3% on gross returns of wool growers, would raise about R20m, the cost of membership of the IWS. The levy was a good deal, given that the licensing to use the woolmark cost more than R70m.

Brock said there was some urgency in the application because SA's continued membership of the IWS had to be confirmed by the end of the month. Failure to do so could result in moves to prevent products using SA wool from carrying the woolmark.

BD 18/3/98

S court decision holds no sway over battle with SA

BD 18/3/98

A US supreme court ruling would seem to support SA in its battle over intellectual property. The Americans, however, do not appear to see it that way, writes Washington correspondent Simon Barber

(96)

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USTR, using its authority,
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y watch list" countries, or at least those that have not taken steps to get off the list.

The US gripe with the medicines law, which seeks to make pharmaceuticals more affordable for SA's poor majority, is twofold. First, the plain language of the act gives Health Minister Nkosazana Zuma the power to abrogate valid drug patents. Second, it permits "parallel imports" of patented drugs obtained at better prices outside the distribution channels of the companies that hold the patents. This, says Pharmaceutical Research and Manufacturers of America (PhRMA), the industry lobby, is a "clear violation" of SA's obligations under the WTO agreement on trade-related intellectual property and a "serious threat to the viability of American pharmaceutical investment in SA".

ZUMA

It may be of some consolation that on the question of parallel or "grey market" imports, no less a body than the US Supreme Court is arguably on SA's side. Consider its unanimous ruling last week in Quality King Distributors Inc v L'anza Research International. California-based L'anza makes pricey hair-care products. To sustain its prices, it only permits its shampoos and other unguents to be sold to beauty salons and cosmetology schools. At least in the US. It does sell at steep discounts to foreign distributors, one of which resold a shipment (apparently bound for Libya with L'anza's knowledge and in violation of US law) to Quality King, a major US wholesaler to discount retail outlets. Quality reimported the goods, which then found their way onto the shelves of various pharmacists back in California.

L'anza sued under the US Copyright Act of 1976, which it claimed had been intended to discourage precisely this kind of "roundtripping" — a common enough practice whereby US distributors exploit manufacturers' multitier pricing systems by acquiring exported consumer goods which companies like Proctor and Gamble have heavily discounted (dumped?) in hopes of increasing brand recognition and sales in foreign markets.

Last year SA "exported" $23m worth of "returned US goods", not counting machinery and aircraft parts shipped back for one reason or another. It is a fair bet that at least a portion of the merchandise was "roundtripped", and because the statistics are based on US, rather than SA, customs data, it is conceivable that some never even reached SA shores. The murkier sort of "U-boat operators", as they are known, do not even bother to ship except on paper.

In any event, L'anza said Quality had violated its copyright by selling its products back into the US without its permission. The 1976 law is contradictory as to whether a US copyright holder has an unrestricted right to control distribution in the US, or whether his rights over the further disposition of any copyrighted item are "exhausted" upon its "first sale". Lower courts ruled for L'Anza. The Supreme Court, over the strenuous objections of US industry (save the discount retailers) and the US government — which complained that its negotiating stance on intellectual property issues worldwide was in jeopardy — reversed the lower courts in Quality's favour and upheld the "first sale" doctrine.

So it is now US law and policy, until such time as Congress rewrites the statute, that owners of intellectual property, while protected against the illegal copying of the property, forfeit the right to set the domestic price of that property once they sell it for export.

Under this doctrine, if universally applied, the SA government would seem to be perfectly within its rights to purchase, or allow its private sector to purchase, patented pharmaceuticals from any legal owner offering the cheapest price.

Not so fast, says PhRMA's Tom Bombelles. The court dealt only with copyrighted items, not patented ones, so the doctrine would not be relevant to "grey market" sales of his industry's products. Besides, he says, if you permit pharmaceuticals purchases outside the patent owners' channels, you risk getting stuck with potentially life-threatening counterfeits. Finally, the industry is already giving the SA government rock bottom prices.

These arguments are not without merit, but neither are the purposes of the SA government. The question is whether the US government is justified in penalising SA for according US intellectual property — the distinction between copyright and patent rights is for lawyers, not people — treatment unanimously sanctioned by the US Supreme Court.

New medicines control council

(96)

Sowetan 25/3/98

By Mokgadi Pela

A NEW Medicines Control Council (MCC) could be established by the end of the year, director-general of health Dr Olive Shisana said yesterday.

Addressing the media in Pretoria on the Report of the Task Team Reviewing the Medicines Regulatory Process, she said the team recommended that it laid the foundations of the new system and that the present order "should cease to exist".

Another recommendation of the review is that within the new Medicines Regulatory Authority, two channels for new drug approval be created.

One element in the new procedure would be for assessing non-orthodox medicines, using appropriate expertise so as to ensure that these are safe and properly labelled.

"It is proposed that the new authority have its own technical secretariat, structured to support the new process. It would be largely self-funding on the basis of fees charged," Shisana said.

Meanwhile, long-time chairman of the MCC, Professor Peter Folb, has expressed his support for the transition process and his loyalty to Health Minister Nkosazana Zuma in developing a system to meet South Africa's needs.

Zuma established a task team on January 19 to do a situation analysis of the functioning of the MCC, including the process of medicines registration. The team consisted of local and international experts and their mandate was to prepare a report to be submitted within three months of the commencement of the review.

The review team also identified a series of shortcomings in drug regulation which have developed in more recent years.

"In particular, there has been a failure of communication between the MCC, policy makers, administrators, the general public and the pharmaceutical industry," Shisana said.

New body to control medicines planned

ARG 26/1/98

The Department of Health has accepted proposals to scrap the Medicines Control Council (MCC) this year and replace it with a new regulatory authority.

In a statement yesterday, the department said MCC chairman Peter Folb had expressed his support for "any transition process that may be required".

However, Democratic Party health spokesman Mike Ellis said the timing of the new proposals was worrying and asked whether there was a causal relationship with Health Minister Nkosazana Zuma's conflict with the MCC.

A team of experts, appointed by Dr Zuma in January to review the regulatory process, said in a report to the minister that the MCC had developed considerable capacity for making sure medicines sold in South Africa were acceptable.

However, they also identified weaknesses in the system, including:

- Frequent failures of communication between the MCC, policymakers, the public and pharmaceutical industry.
- Confusion on division of responsibility for policy and technical matters.
- A large backlog of registrations.
- Potential conflicts of interest.

The experts proposed that a new, autonomous authority be set up by the end of this year. – Sapa

New 'accountable' body to regulate medicines

CT 26/3/98 (96)

JOVIAL RANTAO

DR Abe Nkomo, chairperson of Parliament's health committee, has hailed the findings of a ministerial review team which has proposed drastic changes to the regulation of medicines in South Africa.

The review team — which was chaired by Professor Graham Dukes — yesterday tabled a report which recommended that the present Medicines Control Council (MCC) cease to exist by the end of this year and should be replaced by a new Medicines Regulatory Authority.

NKOSAZANA ZUMA

It proposed that the MCC should be immediately suspended and a temporary council appointed to handle current work until the end of the year.

The team also suggested that the inspectorate of medicines within the MCC should continue, but with a greater degree of autonomy and more adequate resources.

It further recommended that two expert technical committees be established to assess science-based medicines and complementary and traditional medicines.

The team's report has been submitted to Health Minister Nkosazana Zuma, who is expected to comment on Monday.

Speaking after the review team had briefed the committee, Nkomo described the review of the medicines and regulatory system as a comprehensive and balanced piece of work.

"I believe the review will contribute significantly to improve both the structure and the functions of the successor body to the MCC," he said. "The health committee was struck by the backlogs in registering medicines, identified by the review team, and we welcome their suggestions to speed up the process of registering medicines, consistent with internationally defined standards.

"The review team has also suggested broadening drug knowledge and expertise through training. Our committee believes this will go a long way toward building the necessary capacity in universities and colleges across the country, and in addition will open new career opportunities for many for the first time.

"Thanks to this review we will have a medicines review authority which will truly be accountable to the public as well as to the politicians. The review is no reflection on the work carried out to date by the MCC but should instead be seen as building on the work they have done over the years."

Experts query whether Zuma can disband medicines council

(96) BD 30/3/98

Josey Ballenger

LEGAL questions loom over the expected implementation of a proposal to replace the Medicines Control Council with a new drug regulatory authority and suspend the processing of new applications.

Council members, legal experts, pharmaceutical industry and other sources said at the weekend that the health ministry did not have the legal authority to scrap the council, and that pharmaceutical companies could argue they were being discriminated against if drug approval came to a standstill.

The criticism comes in the wake of recommendations made by an independent task committee, appointed by Health Minister Nkosazana Zuma, to overhaul SA's drug regulatory system.

The sources also said members of the council secretariat, who are employees of the health department and are responsible for the council's administration, could not be discharged without abiding by the Public Service Act — and that the forced closure last week of the top secretariat offices was "wholly illegal".

Attorney Zenwill Lacob, a specialist in labour law, said there was "nothing" in the Medicines and Related Substances Control Act, or the recently passed amendments not yet promulgated, that entitled Zuma to disband the council.

However, the new amendments — which are being contested in court and whose accompanying regulations have not yet been drawn up — would allow for the establishment of a new council.

Whether that means the current one could be dematerialised seemed to be a matter of interpretation.

"It seems that Zuma is trying to shut down the council by getting rid of its people and functionaries; she can't (formally) get rid of it other than by an act of Parliament," Lacob said.

"She's trying to make the council's life as miserable as possible, waiting for them to resign," said one pharmaceutical industry source who did not want to be named.

Lacob said if the department wanted to dismiss registrar Johan Schlebusch and his deputy, Chrystel Brückner, it would first have to conduct an inquiry in compliance with public service legislation.

Council members confirmed yesterday that Schlebusch and Brückner were told to accept severance packages — or face disciplinary action on grounds of maladministration. They said the health department had locked and guarded the two offices since Tuesday, when the task force released its report.

Sources said that the council secretariat offices, which house between 60 and 70 staff members, were virtually vacant last week due to the "unpleasant, uncertain" atmosphere.

Speculation is that Schlebusch and Brückner have not yet decided what course of action to take, but that they would likely opt for a "quite exit" rather than fight for their jobs.

Schlebusch did not return calls seeking comment, and Brückner refused to speak to the media.

Zuma's spokesman Vincent Hlongwane denied the secret expulsion, saying: "I do not know anything about those two people .... No walking papers have been served from the minister's office, nor has she authorised anyone to be fired."

Insiders said the removal of Schlebusch effectively brought the council's work to a standstill, as he was the only person authorised to sign certain documents.

"The council has lost its communication; in the short-term, it is an absolute shutdown without the registrar," said council member Prof Antoine van Gelder.

Mirryéna Deeb, executive director of the Pharmaceutical Manufacturing Association, said the task team's proposed timetable for suspending the processing of applications for new drugs or modifications during the transition phase between the council and the new regulatory body, could spark a legal battle.

Council chairman Peter Folb said yesterday he "did not understand the present situation", but urged there be "no compromise on public health in the transition period". Folb, like others, said he was waiting for clarity in Zuma's announcement in Pretoria today. She is expected to endorse the implementation of most, if not all, of the task team's recommendations.

SOWETAN Tuesday March 31 1998

End of the road for MCC - Zuma

(96) Sowetan 31/3/98

By Mokgadi Pela

HEALTH Minister Nkosazana Zuma has given her full backing to recommendations by a task team that has called for the establishment of a new Medicines Control Council (MCC) by the end of the year.

Addressing the media in Pretoria yesterday, Zuma said: "I have also studied the report and indeed accept their broad recommendations."

She said, however, the recommendation on the MCC would be discussed at a meeting between herself and members of the MCC on Thursday.

"Only after that meeting will we be able to take the appropriate measures in this regard. Whatever action will be decided upon will ensure continuity and retention of skills in the work of the MCC," Zuma said.

The decision would also be a recommendation to the Cabinet.

So far, the team has briefed the media and the health portfolio committee of the National Assembly on the contents of the report. The team recommended that the present MCC should cease to exist and that "by the end of 1998, an entirely new medicines regulatory authority should be brought into operation, having a simplified structure based on successful models used abroad".

The team, composed of international and local experts supported by senior officials of the Department of Health, started work in January to review the existing process for the regulation of medicines in South Africa and to make recommendations on this and a number of closely related issues.

She said the team had also recommended that for purposes of "effective transformation and restructuring, two departmental officials be shifted. This is presently being negotiated by the department".

Zuma would not be drawn into further discussions, except to say that both officials were on leave pending the outcome of the negotiations.

The officials are director of medicines administration Professor Johan Schlebusch and his deputy Chrystel Bruckner.

Retail pharmacists knocked by manufacturers who sell direct

(96) CT (BR) 3/4/98

SHIRLEY JONES

KWAZULU NATAL EDITOR

Durban — Retail pharmacists were falling victim to manufacturers who had decided to cut out wholesalers and distribute their own products, Carl Schnell, the outgoing chairman of Alpha Pharm, the pharmaceutical wholesaler, said yesterday.

He said when leading manufacturers cut out wholesalers, they removed the competitive element from the system. This enabled manufacturers to set prices and cancel the discounts passed down the retail chain.

Sandy Jones, the incoming chief executive of Alpha Pharm, said many beleaguered retail pharmacists were already finding it hard to access medicines at reasonable prices without the muscle and backing of leading pharmaceutical wholesalers.

Schnell said the retail side of the pharmaceutical industry was continuing to thin out through mergers and closures. He said over the past two years 60 pharmacies had closed down in KwaZulu Natal alone. This left many rural areas without pharmacies.

Schnell said he believed sophisticated wholesalers provided an important service. About 30 000 lines and 100 000 items were packed a day in the Durban warehouse alone.

Sector swallows corporate change pill

CT (BR) 19/6/98 (96)

ANN CROTTY

Within the week, Aukland, the medical and pharmaceutical group, is expected to announce details of an unbundling that will see the company's assets split between Macmed and Medi-Clinic.

Macmed, which has grown rapidly in recent years during an aggressive acquisition strategy, is expected to buy Aukland's medical supplies business. Medi-Clinic, the country's second largest hospital group, is expected to buy Aukland's hospitals.

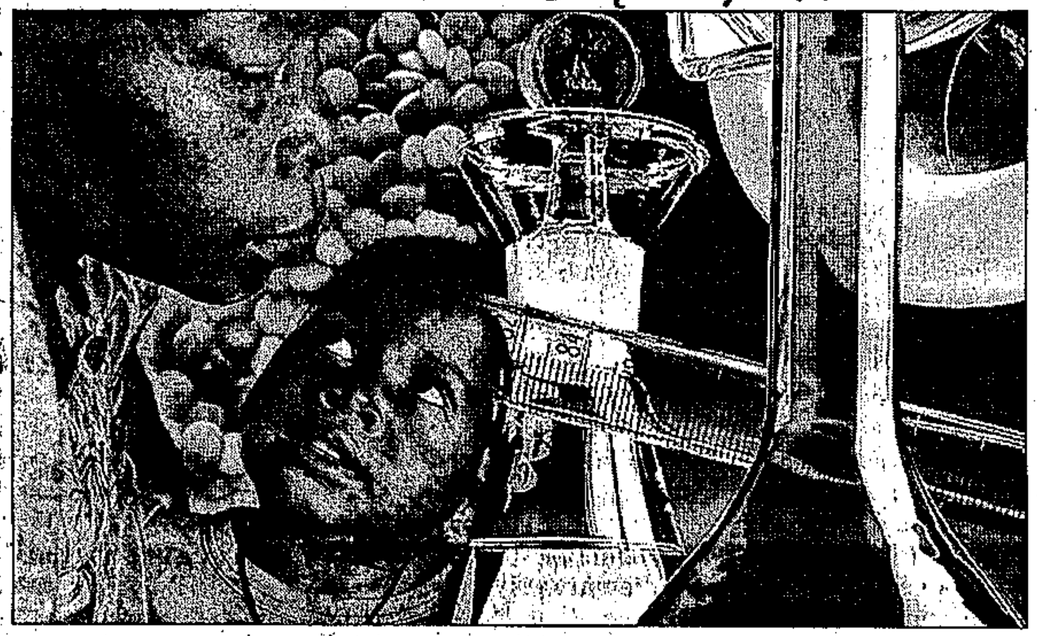
Analysts believe such a deal would value Aukland at as much as 350c a share.

Given the negative market sentiment towards Aukland, its disappearance will not disappoint too many investors.

The Aukland deal follows hard on the heals of the recent announcement by Netcare, the hospital and clinics group, that it was acquiring Excel Medical Holdings, a doctor-owned hospital and medical clinic company, in a deal worth R650 million.

These and a variety of other deals in the past year highlight the dramatic change that is sweeping through the industry. Not too long ago, the JSE's Pharmaceutical and Medical sector could be relied upon to provide a refuge for investors who preferred a quiet life. There was little corporate action but lots of earnings growth as companies reaped the benefits of the almost limitless price increases that were loaded on to a public desensitised by the inefficiency of medical aid management.

The opening up of the South African economy at a time when global pharmaceutical companies were effecting mergers of staggering proportions marked the beginning of inevitable change. The appointment of Nkosozana Zuma as the minister of health quickly reinforced the inevitability of that change. While Zuma exhibited uncertain judgement in some areas, it quickly became apparent she would not allow vested interests to nudge her off course.



That course was directed at achieving the ANC's goal of making affordable, quality health services accessible to the broader population. In his recently published report on the sector, Alec Abraham, a Societe Generale-Frankel Pollak analyst, says the core policy documents tabled by the government to achieve the necessary restructuring of the healthcare system were the white paper on the transformation of the healthcare system and the national drug policy. Both required dramatic changes in the management of health services and consequently precipitated widespread controversy.

"The white paper essentially outlines the state's aim of redirecting resources to establishing a comprehensive non-hospital primary healthcare system which is believed to be the cornerstone of a healthy population," says the report.

The drug policy is devoted to drug prices, which Zuma believes to be a major factor in the high cost of healthcare. Abraham describes the policy's measures:

- The formulation of an essential drug list at the primary care level in the public sector. "This is largely aimed at simplifying the purchasing and administration functions";
- Generic prescription and substitution to encourage the use of cheaper generic drugs where they are available;
- The establishment of a standardised pricing structure of factory exit prices for the various therapeutic categories of drugs. "A single pricing structure will exert pressure on inefficient drug manufacturers and encourage consolidation within the sector to improve cost efficiencies in line with global trends";
- The procurement of drugs and medical supplies by the public sector on the basis of national and international tendering;
- The deregulation of pharmacy ownership; and
- Restricting the extent of promotional activity by pharmaceutical manufacturers. This is a response to the view that much of manufacturers' expenditure has little to do with research and development and much to do with marketing.

While many of the proposals were aimed at the laudable objective of providing cheaper healthcare for the public, Abraham says the fear in the industry is that the pending legislation will seriously impede the operations of companies in the sector, preventing them from achieving above-average returns.

But Abraham argues that this response is inappropriate. He believes "the net effect on most of the South African hospitals and drug companies will at worst be only slightly negative".

The negative investor perception can be attributed to Zuma's poor handling of the issue and the vocal outcry from interested parties. "The large multinational pharmaceutical manufacturers stand to lose the most, given their exposure to the high-priced ethical drug market, which makes them particularly sensitive to many of the sections in the new legislation, which was passed late in 1997."

In the longer-term, Abraham forecasts generally lower costs for pharmaceutical and medical goods and services, and lower medical contribution costs, which will be shared by employers and employees. He refers to early evidence of a sharp reduction in medical aid inflation.

In time, there will be a shift in patient volumes from the public medical sector to the private, enabling the latter to generate greater returns driven through volumes rather than increased prices. While all this is happening there is certain to be much corporate activity in the sector.

Pharmacists wary of sweeping changes to Act

ARG 19/6/98 (96)

The Pharmaceutical Manufacturers' Association (PMA) supports government's goal of ensuring an adequate and reliable supply of cost-effective, quality drugs.

However, the association is concerned that a number of the provisions contained in the new Medicines and Related Substances Control Amendment Act will do little to realise these objectives, but will instead endanger consumer safety and harm the industry.

The PMA contends that the Act abrogates patent protection for the industry, introduces wide and arbitrary powers for the Minister of Health, removes the autonomy and independence of the Medicines Control Council (MCC), allows for unequal registration and safety standards and mandates generic substitution.

While the Act became law on December 12, 1997, its provisions will only take effect at a date still to be determined. It is technically possible that different dates will be used to phase in full implementation of the Act.

According to a PMA position paper: "Despite intensive lobbying efforts by the PMA, our associate international organisation and the governments of the US, Germany, Switzerland and France, legislation was passed without significant changes.

"The members of the PMA have therefore unanimously authorised the PMA to challenge aspects of the legislation in South Africa's Constitutional Court. The PMA is being joined in this action by 40 individual pharmaceutical companies and parent companies are presently lobbying their respective governments to initiate World Trade Organisation action."

The PMA is the trade association representing the research-based pharmaceutical industry in South Africa. The PMA's members account for around 80% of the R10-billion-a-year industry, which employs about 17 000 people. Pharmaceutical exports from South Africa have risen by 903% in the past five years.

The PMA says there is no reason why South Africa should not become a major world centre for clinical trials, thereby attracting further large investments in foreign currency.

"Research investment is easily transferable into other countries and the hostile operating environment that will ensue if the Act takes effect unchanged will certainly see South Africa lose considerable investment."

While the PMA concedes that end-prices of pharmaceuticals to private sector patients are high, the association says they are affected by distribution charges that are among the highest in the world and are beyond the control of manufacturers.

The PMA's major concerns are with regard to intellectual property rights, the powers of the Minister being too broad and parallel importation.

The PMA argues that proposals are unacceptable that force mandatory generic substitution on the public, or which establish a dual system of evaluation criteria and quality standards for drug registration and control and which allow arbitrary interference with legitimate business and trading practices – for example, price fixing, the denial of volume-based discounts and interference with legitimate marketing practices.

The industry does not oppose the use of generics to help government achieve savings at the end of the productive life cycle.

"The use of quality generic drugs can meet patient needs and provide savings to the health-care system, but they should be used in accordance with the doctor's knowledge of individual patient needs and in an environment that encourages market competition," says the PMA.

"We are opposing only the mandatory nature of the principle of generic substitution as contained in the recently approved legislation.

"Furthermore, at a time when South Africa desperately needs to attract foreign investment, the country can ill afford an international challenge at the WTO who will insist South Africa honours its obligations to respect the intellectual property rights contained in the agreement on Trade Related Aspects of Intellectual Property Rights, which the country signed in 1995."

Medical aid gets a growing dose out of what you earn

ARG 19/6/98 (96)

Generic medicines (copies of the originals) form part of a much broader range of issues around health-care funding and cost-effectiveness in South Africa, says Aslam Dasoo, director of policy at the Representative Association of Medical Schemes (Rams).

"Medical aid contributions rose in the past six years from 7% to 18% of employees' pay," says Dr Dasoo.

"Medical schemes have been put on notice by employers and trade unions that year-on-year increases in medical contributions have been too high and must fall in line with salary increases and inflation," he says.

Dr Dasoo points out that the medical scheme industry will spend about R24-billion in 1998 on services rendered its members, who constitute only 15% of the population.

This compares with the estimated R21-billion the Department of Health will spend this year on 85% of the population's health-care needs.

Medical schemes will spend more on their 7-million members than the state can afford to spend on the other 30-million South Africans.

Hospitals account for about 30% of medical-scheme payouts, medical practitioners about 22% and medicines about a third – at least R8-billion is spent on medicines.

According to Dr Dasoo, the resulting attempt by private-sector funders to bring down medical payouts, and the state's emphasis on the provision of affordable primary health care, have created a state of flux in the health-care sector.

"The attempts by funders to manage-down medical costs, together with the state's new strategic approach to national health care and the challenges of transformation, have combined to create an environment of change in the industry.

"In order to manage this new health-care environment, and meet the challenges the disparities in access to quality health-care have created, the public and private sectors will have to act synergistically," he says.

Dr Dasoo believes the use of generic medicines is increasing because of economic pressures on drug budgets.

He says that, in many countries, the practice of generic substitution is strongly supported by health authorities, and South Africa should not be the exception.

> *'Neither Government nor the medical schemes can afford the high prices of original medicines'*

For example, in the United States, up to 65% of all drugs dispensed are cheaper generics, whereas in South Africa less than 20% of drugs dispensed in the private sector are generics – even although generic medicines are up to 60% cheaper than their patented originals.

This adds weight to the belief that South Africa spends too much on medicines, because of the skewed purchasing ratio of original drugs over their generic equivalents.

"Rams has noted the furore surrounding proposals in the Medicines and Related Substances Control Amendment Act, which seeks to intensify the use of generic medication," says Dr Dasoo.

"The fact is neither the Government, nor the medical schemes can afford the high prices of original medicines, and generic medicines are often significantly cheaper.

Dr Dasoo says other positive attributes to the proposals are:

- The responsibility placed on the dispenser to inform the patient of the availability of a generic substitute gives the consumer information they previously did not have.
- The prohibition on generic substitution in certain instances is logical, in that it does not impinge on the rights and independence of the prescribing practitioner.

However, the pricing and mark-up of drugs throughout the distribution chain is also important in keeping down costs.

Dr Dasoo believes the Government's attempts to remove perverse incentives from the medicine distribution chain and introduce a professional fee for pharmacists will contribute to attempts to make health care more affordable.

"This will also create a more competitive ethos.

"Removing perverse incentives is going to cause a major reformation in the way drugs are sold, and is sure to bring down prices."

Rams has taken the policy decision – whatever the outcome of the legal action challenging the Medicines and Related Substances Control Amendment Act – to commit itself to the precepts of the National Drug Policy, and the Rams system of reimbursement, in future, will be based on those precepts.

"We believe it will not only make the industry more competitive, but more ethical," says Dr Dasoo.

Operation takeout: hospitals account for about 30% of medical schemes' payouts, which is a hefty percentage

Generic – what to look out for

In the pharmaceutical industry, "generic" refers to a group or range of products all having the same quantity or strength of the "active ingredient".

That is the chemical part of the medicine that acts against the disease or disorder, according to Barney Sachs, executive director of the National Association of Pharmaceutical Manufacturers (NAPM).

The dictionary defines generic as:

- applicable or referring to a whole class or group, general;
- of relating to, or belonging to a genus, the generic name;
- (of drug or food product) not having a trademark.

While generic medicines are generally cheaper than the branded products, the choice of a medicine cannot be based solely on cost and it is important that the generic substitute and the branded product are equivalent.

Other terms to look out for when purchasing a medicine are:

- Pharmaceutical equivalents are products which contain the same active ingredients and are identical in dosage form, route of administration and strength or concentration.
- Therapeutic equivalents are pharmaceutical equivalents that can be expected to have a comparable therapeutic effect when administered to patients under the conditions specified in the package.
- Bio-equivalent – when a generic medicine is therapeutically equivalent to the innovator's product.
- Bio-availability – if the active drug in a formulation can be demonstrated to be absorbed into the bloodstream at the same rate, and in the same amount as another preparation, the therapeutic effects of the two products will be the same.

ARG 19/6/98

Quality care for low-income earner

Affordable, good quality health care is now within the reach of low-income earners thanks to a ground-breaking deal between Norwich Healthcare and the Soweto Independent Practitioners' Association (SOIPA).

Together they have launched Real Health, a managed health care company which markets and administers an affordable managed health care product providing medical cover to all, especially formally employed and self-employed people for whom medical cover was too expensive.

Real Health's main market is categorised as "blue-collar and unstarched white-collar" workers earning at least R1 500 a month in the formal employment sector who have the choice of contributing to their company's medical aid schemes managed by Real Health.

Doctors registered with Real Health may also sell individual medical cover policies to their patients which will give them the same benefits as the formally employed.

Real Health aims to attract 100 000 people (members and their dependants) to the scheme before the end of 1999. The product is priced at an affordable level for low-income earners yet offers the full spectrum of benefits. The few limitations apply to highly specialised procedures such as specialised dentistry.

Dr Kenosi Mosalakae, chairman and a founding member of SOIPA and executive chairman of Real Health, says that providing affordable health care to low-income earners will have a major impact on health services. Patients will source treatment from the private sector, thus relieving pressure on government facilities, resulting in better treatment for the poor at hospitals and clinics.

Generics: Zuma holds firm

ARG 20/6/98 (96)

Health minister adamant on delivering cheaper medicines to poor

South Africa spends the second-highest amount in the world on medicines. Health Minister Nkosazana Zuma wants to bring down these costs. Consumer Writer **Shalo Mbatha** investigates ...

One of the ways Health Minister Nkosazana Zuma and her department want to use to bring down the cost of medicines is "parallel importing", and provisions for this have been made in the new Medicines and Related Substances Control Amendment Act.

But, what is parallel importing and what are the positive and negative implications?

The act allows the Government to import branded drugs from any factory in the world, where they are cheaper than those available in South Africa.

Pharmaceutical multinational companies manufacture medication in several factories around the world, then designate which lots go to which countries at different prices. This effectively sets prices for every country in the world.

As far as the Department of Health is concerned, manufacturers exhaust the right to set the prices after selling to the first wholesaler, making it legitimate to scour the world for cut-price brands. "The South African pharmaceutical manufacturers have been trading in a protected environment for many years and are uncomfortable with change. So long as the local product is costly and the manufacturers refuse to bring the prices down, we shall soldier on," said a spokesperson from the Department of Health.

The Pharmaceutical Manufacturers' Association (PMA), which represents the large multinational pharmaceutical companies in South Africa, is strongly opposed to the act. The PMA and nearly 50 co-applicants have challenged it in court. The respondents are not only the minister of health and her two directors-general but the president, deputy president, the Speaker of Parliament and the minister of finance.

South Africa is not the only country to legalise parallel importing. Argentina, Brazil, India and many others allow parallel imports.

For the majority of the poor that depend on public health facilities, it is seen as a means to quality and affordable medicine.

The African National Congress Government promised the needy affordable, quality health care once in power. "The Government finds the pharmaceutical manufacturers' stance laughable. We live in a market forces-driven economic system, and scouring the world for cheap supplies for the public sector is free trade, isn't it?" Dr Zuma was quoted as telling the New York Times recently.

The health ministry's consultant, Ian Roberts, emphasised the ministry had no intention of abrogating patent rights and said South Africa was a signatory to the Trade Related Aspects of Intellectual Property Rights – and one of the clauses of this treaty was the right of importation.

Kobus Nel, the chief executive of Pharmacare, the largest supplier of generic medicines to the Government, said his company was not worried about the impending foreign competition, but added: "I'm afraid some local manufacturers will not be able to compete with foreign imports."

The PMA argues that parallel importation would also allow the flooding of the market with cheap, expired and repackaged counterfeits as well as substandard medicines.

"Allowing parallel imports of medicines into South Africa could create opportunities for unscrupulous operators to import counterfeit products through the alternative distribution systems that would be established" says a PMA discussion document.

The Government, on the other hand, says the dangers will be lessened because it will insist on a "paper trail" with medication imports to prove they are genuine.

The Representative Association of Medical Schemes (Rams) policy director, Dr A Dasoo, rejects the manufacturers' fears about counterfeit drugs.

Dr Dasoo said Rams was "stupefied" by some of the assertions by the manufacturers about the alleged levels of fake drugs in Africa.

"Firstly, this is well nigh impossible to measure and secondly, a significant proportion of drugs entering some African countries are produced right here."

He said Rams agreed with the Department of Health that "international tendering will increase access to quality medicines".

Dr Dasoo added: "Let's face it, the provision of quality healthcare is not profitable for the Pharmaceutical Manufacturers' Association – that is why they are vehemently opposed to it."

STANDING HER GROUND: Dr Zuma wants to bring down medicines costs

Direct distributors may be investigated

Pharmacists level charge of monopoly

CT(BR) 22/7/98(96)

ADELE SHEVEL

Johannesburg — Pharmaceutical wholesalers and pharmacists were expected to submit their complaints by Friday to the Competition Board about direct pharmaceutical distribution systems, Pierre Brooks, the board chairman, said yesterday.

Pharmaceutical wholesalers had expressed concern that the direct distributors were "anti-competitive" and monopolistic, Brooks said. He said pharmacists had also indicated they were not happy with direct distributors.

Once all parties had provided their arguments, the board would decide if a formal investigation was required, Brooks said.

The issue came to the fore with the announcement this week that a second large direct distributor was about to come to the market, impinging on the traditional turf of the wholesalers.

International Healthcare Distributors (IHD), which comprises nine multinational drug producers, already has about 30 percent of sales.

Project Nasa, a newcomer comprising five multinationals and one local producer, expects to corner 25 percent of market share. But it is adamant that its products will still be available to wholesalers.

Leon Schonknecht, the chairman of UPD, the pharmaceutical wholesaling company, said yesterday the shake-out in pharmaceutical warehouses over the past three to four years had left about 3 000 people jobless and had led to the closure of about eight warehouses, with more casualties expected.

Schonknecht said the direct distribution system employed by manufacturers had effectively eliminated competition at a distribution level and limited pharmacists' choice of distributors.

Pharmacists also expressed concern yesterday. Graeme Wald, an analyst at Merrill Lynch, said smaller pharmacists were being further squeezed by the need to implement more sophisticated information technology systems and by the shift to payment based on professional service fees.

Trevor Milton, the chief executive officer of Link Investment Trust, said wholesalers in the industry operated at low margins and their profitability was questionable.

He said wholesalers would be knocked further as another large company was expected to join the IHD fold.

But John Bartlett, Project Nasa's spokesman, said: "The role of intermediaries in many industries is under pressure.

"If this channel cannot sustain itself, it is up to the manufacturers to make sure they will have a channel through which to distribute their products."

He said the rules of the game were changing, and new rules required new strategies. This change had been forced by legislative and other marketing circumstances in order to ensure supply, Bartlett said.

Johan Niehaus, the chief operating officer of IHD, said the devaluation of the rand had forced manufacturers to increase prices. "The rate of increase of the prices of the goods rose slower than the combined effects of the factors influencing the rise," he said.

:iation junior flyweight champion
s Sydney Ellerine during the official
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PIC CLEMENT LEKANYANE

Train strike off after agreement

Sowetan 30/7/98

By Mzwakhe Hlangani

A POTENTIALLY crippling nationwide strike planned for tomorrow was averted last night when six trade unions representing about 10 000 workers and management of Metrorail reached a last-minute agreement over wage increases.

Only one union, the SA Footplate Association (Safsa) with a membership of only 1 700, including train drivers, technical workers and train guards, rejected Metrorail's final offer.

Safsa spokesman Mr Chris de Vos said the union's demands were not met and it would report back to its members for a new mandate.

The deal followed lengthy talks in Johannesburg yesterday between the SA Railways and Harbours Workers Union, the Black Allied Workers Union and the Technical Allied Workers Union (Tatu) in a bid to resolve the wage dispute.

The signatories said social commitment was the major criterion for reaching consensus among all the parties since the strike would affect the poor communities more than it would Metrorail's management.

Metrorail executive human resources director Mr Mark Ganstein-Bein pointed out that the deadlocked negotiations were reopened after chief executive officer Mr Z Jakavula and Sarhwu general secretary Mr Derrick Smoko had started informal talks with the aim of "putting out the flames that could be caused by the strike".

He said the doors would be left open for Safsa to join the fold as it had reneged in the final minutes.

If the union decided to go on with the strike, minimal disruption could be expected as buses had been hired in anticipation of the strike by some train drivers.

The terms of agreement include a 7,5 percent increase backdated to March 16 1998 and 3,5 percent to be effective from November 16 1998. There would be a further 5 percent from March 16 next year.

Both parties agreed to negotiate a deal on profit-sharing among the workers.

Hospital sets quotas

(96) Sowetan 30/7/98

By McKeed Kotlolo

A CRISIS is gripping the Pretoria Academic Hospital, one of the capital's busiest hospitals, following an acute shortage of pharmacists caused by resignations.

As a result, hospital management has introduced a temporary quota system with a maximum of 150 outpatients accepted each day.

Dr Julius Kunzmann, the Pretoria hospital's director, said yesterday such situations occurred from time to time when pharmacists left to join the private sector which offers lucrative salaries.

Although the Pretoria Academic Hospital has managed to cope with the situation in the past, the recent departure of four pharmacists in a short period had dealt the institution a serious blow, he said.

Kunzmann said the issue of improving hospital salaries was out of their control since it was negotiated at the national level.

The hospital's chief medical superintendent, Dr Zola Njongwe, said the new quota system came into effect on Monday in an attempt to ease the pharmacy's load.

She said the hospital had 32 approved pharmacist posts, but only nine were filled. "Of the remaining nine, three have resigned their posts and would be leaving us at the end of the month," Njongwe added.

The departure on maternity leave at the end of this week of one of the remaining six pharmacists would worsen the situation.

She appealed to residents, in particular those from the eastern and central suburbs of Pretoria, to take note of the limited number of patients to be admitted a day at the general outpatients clinic.

Njongwe appealed to qualified pharmacists "who are able and willing to assist us on a full-time or sessional basis (with remuneration)" to urgently contact Mrs A Engelbrecht on telephone number (012) 354-2235.

Defence industry urged to form alliances

BD 3/8/98

Pule Molebeledi

THE key to promoting SA's defence industry in the international defence and civil markets is to form alliances, according to Carol Reed, editor of the UK-based Flight International magazine.

Speaking at a two-day African defence summit meeting in Midrand last week, Reed said economic necessity was forcing defence industries around the world to compete and to co-operate across frontiers. Shrinking defence budgets worldwide and the high costs of weapon development required economies of scale and technology sharing, she said.

Reed said many US and European defence industries were increasingly looking to expand their market share and to gain economies of scale in technology and manufacturing. This was done via mergers and acquisitions, strategic alliances and joint ventures at national and international levels.

Reed said the countries' governments had aided the process through the privatisation of state-owned companies, the liberalisation of merger policy and other incentives for rationalisation.

She said globalisation meant companies could not keep their technology out of the hands of competitors, especially as many companies relied on a range of vendors. "You cannot do without the technology and skills of others. You cannot even keep your own technology for long," she said.

However, she cautioned that many alliances did not take off, either because of fears that they meant easy access to domestic markets or because they were viewed as a "quick and dirty" means to access foreign markets.

Reed said the US was spearheading the globalisation trend while the pace of consolidation of the supplier base in Europe had been slow and piecemeal.

Intra-European arms transfers between 1984 and 1994 amounted to $17,4bn while US arms imports registered $45,1bn.

Fluoridation gets thumbs-up

(96)

Business Day Reporter

BD 3/8/98

THE SA Dental Association supported the health department's plans to add fluoride to SA's water supply to prevent tooth decay.

Tooth decay was expensive, with "millions" of school and work hours lost due to treatment.

Extensive scientific documentation confirmed that worldwide fluoridation of public water supplies was the "safest and most cost-effective, community-based measure of combating tooth decay".

SALES AND MARKETING

HOTEL PROMOTIONS

Hospitality Marketing International require the services of a **DYNAMIC** Sales and Promotions orientated Manager to be involved in the marketing of Hotels.

The successful applicant will be:
Aged 25-35, well-spoken with good communication skills, have a high degree of integrity, be available for transfer within South Africa and be in possession of a degree/diploma.

SA NEWS DIGEST

PHARMACEUTICALS

(96)

Wholesalers withdraw Supreme Court submission against direct distributor

Pharmaceutical wholesalers this week had withdrawn their submission at Supreme Court level alleging collusion and problems with pricing and supply against International Healthcare Distributors (IHD), the direct distributor, Trevor Phillips, the executive director of the National Association of Pharmaceutical Wholesalers, said yesterday.

CT (BR) 21/8/98

He said the withdrawal was because the pharmaceutical wholesalers' relationship with IHD had improved, as wholesalers had been given access to distribute certain products of about a third of the 10 distributors. Phillips said IHD had received many complaints from pharmacists and doctors about difficulty in accessing certain products. Johan Niehaus, IHD's chief operating officer, said the company would "re-evaluate the whole situation", referring to the charge that IHD was anti-competitive and monopolistic placed at the Competition Board. IHD had said they would not respond to the charge until a decision had been taken at Supreme Court level about allegations of collusion. — *Adele Shevel, Johannesburg*

New medicine regulator proposed

(96)

Draft legislation paving the way for the establishment of an independent medicine regulatory authority, to replace the Medicines Control Council, was tabled in Parliament yesterday.

According to a memorandum attached to the South African Medicines and Medical Devices Regulatory Authority Bill, the regulation and registration system for medicines and medical devices – established by the 1965 Medicines and Related Substances Control Act – was unable to meet the challenges currently facing a medicines regulatory system.

The proposed new body – the South African Independent Medicines and Medical Devices Regulatory Authority – will attend to the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, complementary medicines, veterinary medicines, medical devices, clinical trials and related matters.

The authority will have the sole responsibility for the technical evaluation, regulation and registration of medicines and medical devices. In terms of the bill, the authority has to appoint standing technical committees consisting of experts and people with skills and experience in the area of medicines and medical devices.

A board appointed by the minister of health will be responsible for managing the authority.

The bill addresses the confusion regarding the regulation of veterinary medicines, by removing stock remedies from regulations in terms of the Farm Feeds, Fertilisers, Agricultural Remedies and Stock Remedies Act. Veterinary medicines would now be regulated by the authority, it says.

The bill also gives long overdue attention to the proper recognition and regulation of complementary medicines. As the disciplines of orthodox and complementary medicines were in many ways different, the bill provides for determining different guidelines for evaluating orthodox medicines, complementary medicines, and veterinary medicines or devices. – Sapa

ACW 4/9/98

Druggists oppose doctors' lists

ADELE SHEVEL

Johannesburg — Representatives from major multinational pharmaceutical companies met on Friday to fight doctors' demands for payments to ensure their products stayed on prescription lists.

Pharmaceutical manufacturers claim that doctors, through independent practitioner associations (IPAs), are forcing them into a corner as the lists which doctors prescribe from, known as the formulary, include products covered by medical aid schemes.

In order for these products to remain on the formulary, manufacturers have to pay an initial listing fee and rebates based on incremental usage to a formulary management company, which handles the formulary on behalf of the IPA.

Certain medical aid schemes charge additional payments if items not included on the list are prescribed by doctors.

Several sources from multinational drug companies, who do not want to be named, have called for a halt to this practice. One insider has described the practice as verging on "extortion".

The IPAs claim they are working within the managed healthcare system to pass on the benefit to the patient, but manufacturers contend the customers receive no financial benefit from the practice.

The meeting on Friday was spurred by the implementation of a new scheme by African Health Synergy, a joint venture between Sanlam and the South African Medical Care Coalition (SAMCC).

The SAMCC is backed by medical aids Sanlam, Southern Healthcare, Telemed and Old Mutual Healthcare.

Pharmaceutical companies have until September 15 to decide whether or not to join the scheme.

Danie Struwig, the formulary convener at the SAMCC, said African Health Synergy's formulary was in existence and had no payments for any company to be listed. "Our system should not be confused with other mechanisms prevailing in the market."

Struwig said manufacturers would pay 0,5 percent of the company's volume sales. Manufacturers have been asked to consider paying 0,5 percent of the wholesale price of the product every two months as the listing fee. In return, manufacturers would receive information to be used as a platform to start treatment protocol.

(96) CT(BR) 7/9/98

Pharmacy council operational soon

(96)

THE new SA Pharmacy Council, intended to regulate the profession and to serve as a controlling body for registered pharmacists, is expected to begin operating soon, following the recent election of nine of its 25 members.

Interim pharmacy council registrar Jan du Toit said the interim council, whose members were appointed by Health Minister Nkosazana Zuma in 1995 to assist in drawing up legislation to transform the profession, "had achieved its goal" and would disband on October 20.

The new council's nine elected members are: Gary Köhn, Gert van der Vyver, Valerie Beaumont, Dr Mariette Lowes, Ray Pogir, Dr Natie Finkelstein, William Bannatyne, Andries du Preez and Willem Bezuidenhout. Zuma must appoint 16 other members.

BD 22/9/98

The objectives of this new statutory body will be to promote pharmaceutical care and to develop and maintain high standards in pharmacy.

Competition Board looks into SABC, pharmacies

(96) BD 5/2/99

Janet Parker and Amanda Vermeulen

THE Competition Board has launched two new investigations, one targeting the SA Broadcasting Corporation (SABC) and the other some of the largest pharmaceutical manufacturers operating in SA.

According to a complaint lodged with the Competition Board by the Association of Facility Owners, the SABC is insisting that television productions made for the SABC's three channels be produced using the SABC's Henley facilities.

The board said the practice was likely to limit the ability of independent facility houses to compete for the business of independent producers and would constitute restrictive practices.

SABC spokesman Enoch Sithole confirmed yesterday that part of the corporation's programme commissioning process was to stipulate that as much as possible "... any production should be done using SABC facilities".

The SABC's Henley and airtime studios had become quieter and less profitable since 1997, when the SABC began to outsource much of its production.

However, Mfundi Vundla, chairman of the Independent Producers Organisation of SA, said it was not the fault of the independent industry that the SABC was burdened with redundant facilities. Independent producers and facility owners were losing business because of the SABC's strong-arm tactics, he said.

Vundla said the independents were committed to cultivating the industry, had a good work ethic, and could offer better deals and service than the SABC.

Meanwhile, the announcement of the board's investigation into drug manufacturers confirmed earlier reports of a pending investigation following complaints stemming from the establishment of two distribution companies.

The board said the agreements between the manufacturers and the two distribution companies — International Health Care Distributors (IHD) and Synergistic Alliance Investments (SAI) — appeared to constitute restrictive practices as defined in the Maintenance and Promotion of Competition Act.

The board decided to investigate as restrictive practices in the pharmaceutical industry could affect the prices of prescription medicines.

This dispute is centred on claims that SAI and IHD are single channel distributors that bypass wholesalers.

Comment: Page 7

Health boss to tackle long queues

DI CAELERS
HEALTH WRITER

(96) ARG 20/7/99

The Western Cape health department has a shortage of pharmacists which is adding to the woes of patients at the province's health facilities.

Yesterday, during visits to Tygerberg Hospital and the Michael Mapongwana community clinic in Khayelitsha, provincial Health Minister Nick Koornhof said he was struck by long pharmacy queues at every institution he had visited.

He planned to take urgent action to prevent these queues, which added many hours to patients' visits, sometimes even forcing them to return the following day.

The province had a shortage of pharmacists and even when vacant posts were advertised there were often no applicants.

"The salaries we offer are just too low compared with what pharmacists command in the private sector," said Mr Koornhof.

Edmund Michaels, senior medical superintendent of the Community Health Services Organisation, under which the Michael Mapongwana clinic falls, told Mr Koornhof the unit had been intended to provide a 24-hour service, but because of staff shortages it had never achieved this in the four years it had been open.

"Posts have just never been created to allow us to open this clinic 24 hours a day," said Dr Michaels.

Discussing his visit to Tygerberg Hospital, Mr Koornhof reiterated his stance on the importance of public-private partnerships in health care, particularly in respect of academic hospitals.

"If we lose the academic hospitals, they will be gone forever. It will never be possible to build them up again from scratch so we cannot allow that to happen.

"I have often spoken of the importance of getting public-private partnerships going and I believe these can really benefit institutions like our academic hospitals."

Pharmacy students to serve too

(96) ARG 19/8/99

POLITICAL CORRESPONDENT

Pharmacy students will be obliged to perform compulsory community service in line with their counterparts in medicine and dentistry, after the Cabinet yesterday approved an amendment to a Bill to this effect.

The Pharmacy Amendment Bill says newly graduated pharmacists should undergo one year's paid community service before they are entitled to practice. This community service is planned for introduction in 2001.

Newly graduated doctors are already doing a year of compulsory community service.

Dentists began voluntary community service in June this year, and this will be compulsory from next year.

The Cabinet also approved the Higher Education Amendment Bill which will allow the minister of education to intervene in tertiary institutions that are badly managed.

The minister will be able to appoint the director general as registrar in a troubled institution.

The Cabinet also approved the National Student Financial Aid Scheme Bill. – Parliamentary Bureau

Pharmacists to fight 'flawed' act

CT (BR) 23/9/99 (96)

ADELE SHEVEL

Johannesburg – The Pharmaceutical Manufacturers' Association (PMA) said yesterday it would proceed with legal action against the government if contentious elements in the Medicines Act allowing for compulsory licensing and patent abrogation remained unchanged.

However, Mirryena Deeb, the chief executive of the PMA, stressed that legal action was a last resort.

The PMA, which represents 41 pharmaceutical companies, this month temporarily suspended its constitutional challenge after Manto Shabalala-Msimang, the health minister, said some legislation would be returned to parliament for review.

President Thabo Mbeki told the United Nations this week that South Africa would implement the law after talks with the companies involved, suggesting their concerns would be dealt with by regulations. South Africa would conduct "parallel imports" outside of channels authorised by the patent holder.

Deeb said the regulations could not address the defects contained in section 15c, the contentious clause abrogating patent rights. Regulations could only enforce the details as provided for in the act, not change them.

"It is vital to ensure the language in the main act is Trips compliant, conforming also to the South African patents act and constitution. The wording has to be unambiguous and clearly reflect the intentions of government.

"We welcome President Mbeki's reported offer to sit down and talk to us about our concerns," said Deeb. "The president needs to be sensitive to an industry which represents a R17 billion a year investment in this country, particularly if he is seeking to encourage other investment."

The department of trade and industry said earlier this week the government would honour its obligations under the Trips agreement in implementing the Medicines Act, which permits parallel importation and compulsory licensing of patents for pharmaceuticals.

"Abrogating patent rights to grant compulsory licences to third parties would simply negate investor confidence, thereby endangering any sustainable supply of quality treatment," said the PMA.

Community service mooted for pharmacists

JANET HEARD (96)

ST (CM) 14/11/99

MORE than half the state pharmacist posts in some provinces were vacant, underscoring the need for pharmacists to do community service, Health Minister Manto Msimang-Tshabalala said at the weekend.

Msimang-Tshabalala said that in the Free State and Gauteng respectively, 52 percent and 47 percent of the posts were vacant.

"The situation is worse in provinces like the Eastern Cape and the Northern Province," she told health sector officials in Cape Town.

An amendment to the Pharmacy Act, which will require graduates to complete a year's community service, will be debated in Parliament on Thursday.

A similar law has already been passed for doctors and compulsory service is also on the cards for lawyers and dentists

"We will also be exploring a further expansion of this programme to include physiotherapists, occupational therapists, speech therapists and psychologists."

Releasing details of a review of the public health service, Msimang-Tshabalala said the pressure placed on budgets by population growth and the HIV/AIDS epidemic was likely to be substantial. Between 2000 and 2002, total real spending across all of the nine provinces was projected to rise by 2,8 percent — almost R700-million — but this increase would be diluted to 0,4 percent — or a mere R3 per person — by population growth.